
Disclosure File

P0011367.00

DEFLECTABLE CATHETER WITH NOVEL LUMEN CONSTRUCTION

Division: LT021

Status: O

Attorney: ELB

SubDivision: LT021

SubStatus: REV

Outside Counsel:

Group: CRM

Priority: X

Submitted:

Approved:

Last Review:

Goode, Johnson E.

Spear, Stanten C.

Kelley, James F.

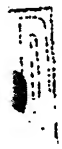
Minutes:

Other Information:

Date

Description

Information





Medtronic

LT021

ELB

P-11357.0C

INVENTION DISCLOSURE FORM

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This is a WORD Template form. Press enter or tab to move to each field. Please fill out this form as completely as possible. If the allotted space is not sufficient, use a separate sheet. Have your manager sign the form and forward it to the Patent Section of the Law Department, MS301. Please attach any drawings and technical descriptions that are available and assemble copies of the background articles, books, advertisements, etc. for use by your patent attorney.

1.	Inventor(s)	Employee	Mail	Home Address (Include Zip Code)
	Full Name(s)	Number	Stop	
	Johnson Eric Goode		B230	6425 Polaris Ln N, Maple Grove, MN 55311-4320
	Stanten Charles Spear		B248	1752 Chatham Ave., Arden Hills, MN 55112-3226
	James Frederic Kelley		B230	13000 Nightingale Street NW, Coon Rapids, MN 55448

2. Title of Invention: Deflectable Catheter with Novel Lumen Construction

3. Summary of the Invention:

A deflectable catheter with a thru lumen has great clinical utility in left heart therapy delivery procedures by allowing a guide wire or contrast agent to be used during the procedure while using the same deflectable catheter. This ability increases the physician's situational awareness and therefore increases the probability of success and decreases the chance of venous trauma. A common drawback of having a deflectable catheter with a thru lumen is that the deflection mechanism takes up so much interior lumen space that in order to make the lumen large enough to be useful, the outer diameter of the catheter would increase to unacceptable dimensions.

Pull wires are commonly applied to catheters to enable the catheter to be deflected by pulling back on the pull wire which in turn compresses the distal end of the catheter, creating the deflection. If one needs to incorporate a thru lumen into the catheter it is common practice to segregate the pull wire from the lumen by use of a multi-compartment catheter, with separate compartments for the pull wire and thru lumen. This method has the disadvantage of reducing the amount of area available for the thru lumen, due to the wall thickness of the segregated compartments, which in turn reduces the maximum lumen diameter that can be used at a given catheter outer diameter.

This invention solves the above problem by increasing the effective size of the pull wire member by containing the distal end of the pull wire in a spring, or other compressible member, and using this to hold the pull wire in place in the lumen of the catheter. The spring, or compressible member, is attached to the catheter member at 1 or no ends of the catheter shaft to allow relative movement between the spring and pull wire. This allows the elimination of the individual compartments and their associated separation walls and will maximize the size of the thru lumen for a given catheter outer diameter. It is no longer necessary to separate the pull wire from the through lumen and a common lumen profile can be used to contain both.

4. How have others addressed this problem (List and attach any patents, books, articles, devices, Medtronic or competitor's products, or other background materials you used or which may be prior art)? A prior Medtronic device, the 9210 catheter, employs a bi-lumen tubing. A steerable member or guide wire is placed in the outer tubing which then directs the other, non-obstructed tubing. This method is fundamentally different from the disclosed method in that both lumens are still segregated with the associated wall thickness. Another company Daig/St. Jude employs an X shaped lumen which provides for a flat spring or other flat member that separates the lumen into two compartments. This device does not incorporate a thru catheter lumen. The LumaCath, from Irving Biomedical Inc., has a thru catheter lumen construction that incorporates a interior tubular member that surrounds the thru catheter lumen.
5. The invention is described on pages 23-25 of Lab Notebook No. 10363 (preliminary, still contained separate bending beam)

6. When was a device built which included the invention?
Who built it? John Goode Where is it? Medtronic Rice Creek Center
Who has supporting documents? John Goode
Who witnessed tests? Stanten Spear, John Goode, Bob Colbert When and where? May, 2002 Medtronic Rice Creek Center RA lab
7. Discuss the problems which the invention is designed to solve, referring to any prior devices of a similar nature with which you may be familiar. Problem was creating a deflectable catheter with a thru lumen that would fit within dimensional constraints of existing therapy delivery devices. The outer diameter of the catheter has to be 7 Fr or less to allow passage through a 6218A guide catheter. Also, the thru lumen ideally would allow passage of introducer type guide wires, which range up in size to .038 inches, with .025 and .035 inches being most common. Preliminary testing with a .021 in thru lumen indicated that not enough contrast could be passed to be clinically useful. These objectives had to be met while still allowing the deflectable catheter to track over a guide wire, ideally an EP type guide wire between .014 and .018 inches. This has the clinical benefit of leading with a guide wire to minimize risk of venous trauma and allowing for venous subselection. The tip of the deflectable catheter also must be radio opaque to allow visualization using fluoroscopy, and be soft and non traumatic.
8. State the advantages of the invention over presently known devices, systems or processes. The device has a .039 in diameter thru lumen. This is large enough to accommodate up to a .035 in diameter guide wire and large enough to pass clinically useful amounts of contrast. The radio opaque and echo-genic tip eliminates the need for a metallic marker band at the tip, decreasing chance of venous trauma and reducing product costs. The tapered tip facilitates tracking ability over guide wires. The extrusion profile is simpler than competing devices and maximizes the size of the thru lumen at a given catheter outer diameter.
9. List all known and other possible uses for the invention. Therapy delivery devices requiring a lumen, including catheters, leads, dilators, diagnostic catheters or probes, implantable sensors, balloon catheters.
10. Specifically describe the invention and its operation. You may use and attach copies of sketches, prints, photographs and illustrations which should be signed, witnessed and dated. Use numbers and descriptive names in descriptions and drawings. The distal extruded lumen profile is as shown per the drawing. A spring encloses the pull wire. This increases the effective size of the pull wire member to hold the pull wire in the "cut out" area of the catheter lumen profile. The spring may be connected at one or zero points to the catheter side shaft. The spring cannot be connected at more than one location as it must be free to move relative to the pull wire and catheter shaft. In practice, the spring is connected at the distal end via adhesive or polymer backflow from the anchoring band/pull wire junction. The tubing is also fixed on one end (distal) and also cannot be connected between the braided shaft and the deflectable shaft as it must be free to slide with in the catheter body during deflection. The tip section is 48D PEBAX loaded with jet milled tungsten carbide to be both radio opaque and echo-genic. The outer diameter of the deflectable catheter is tapered like a dilator to assist in passage through restricted veins or ostia.

There are several methods in which this catheter can be deployed. The general system consists of a fixed shape sheath, steerable catheter, a guide wire and a lead. The general method includes a sheath that is back loaded on to the steerable catheter with a guide wire inserted into the lumen of the catheter. The outer sheath could be straight or any one of a number of variety of curves such as a MB2, Amplatz or multipurpose. The combination provides multiple degrees of freedom and flexibility to cannulate the coronary sinus. The guide wire is extended beyond the end of the catheter and is used to probe for the cs ostium. Contrast media may also be injected to assist in the location. Once the cs cannulated, the guide wire is pushed distal and the catheter advanced into the cs. The outer sheath is then advanced into the ostium and serves as a work station for tool exchanges. The catheter is removed and the venogram balloon placed over the wire and a venogram preformed. A physician may elect to remove the guide wire and inject contrast media directly into the venous structure. Depending on the size of the guide wire used, it is reinserted in the catheter and advanced to the targeted sub-vein. The wire is advanced distal in the sub-vein and the catheter and sheath advanced over the wire. The catheter is removed, leaving the sheath and guide wire behind. Depending on the size of the guide wire, the lead is advance directly over the guide wire into position.

This catheter could also be used to deliver small diameter leads to the right side chambers. The ability to push contrast media through the lumen also allows the physician to visualize structures with the heart for precise placement of diagnostics and therapeutic devices.

Another method is in the performance of pulmonary vein ablations. This catheter could be used to safely locate and puncture the fossa ovalis to access the left atrium. Once the puncture is made a sheath would be placed and the catheter advanced to the pulmonary veins. Contrast media is injected through the center lumen to identify the pulmonary vein ostium.

This catheter may also prove useful in cannulating the coronary sinus ostium when the ostium is partially occluded by a Thebesian valve by using a guide wire to pass by the valve and tracking the catheter over the guide wire. The same would apply more distally in the cardiac anatomy by providing a method for passing through the Valve of Vieussens. The ability to visualize using contrast and track past obstructions using a guide wire enables placing the delivery system closer to the final pacing site.

11. List all features of the invention that are believed to be novel. 1) Using a spring or other compressible member to contain the pull wire thereby increasing the effective size of the pull wire member to hold in place in lumen. 2) Attaching the spring on one or zero ends (not both ends, spring must be free to move relative to pull wire and tubing). 3) The tubing does not connect the braided shaft to the deflectable shaft, again must be free to slide within catheter body during deflection. 4) Tapered tip feature in a deflectable catheter, increases in diameter (distal to proximal) to facilitate passing through restricted space such as the coronary sinus thebesian valve, venous valves, etc. 5) Anchoring pull wire in body of catheter, not tip. 6) Radio opaque and echo-genic tip, eliminating the need for metallic marker bands, or separate radio opaque and echo-genic fillers in the polymer. 7) The catheter taper provide back-up support for the guide wire. 8) The catheter provides back-up support for the outer sheath.

Method claims:

1) Using steerable catheter with guide wire and delivery sheath to cannulate coronary sinus and establish workstation for delivery of venogram balloon catheter and leads, with or without guide wire 2) Subselecting branch veins by selecting with guide wire and tracking over 3) Performing venogram without necessity of exchanging with a venogram balloon catheter 4) Placing guide wire in final selected site and advancing lead over guide wire. Lead could first be loaded onto an extension wire via the connector end with the extension wire then being connected to the retained guide wire. Then the lead would be advanced over the retained guide wire in the normal manner. This allows Medtronic's OTW lead to be delivered without going backwards through the distal seal. Once the guide wire loading tool is available, could load OTW lead directly over the retained guide wire. 5) Delivery small diameter leads or other devices directly through the steerable catheter 6) Use the catheter to perform Pulmonary Vein ablations by puncturing the fossa ovalis via puncture tool passed thru catheter and then securing left atrial access via guide sheath passed over steerable catheter. 7) Catheter has unique ability to pass thru partially occluded venous structures such as a Thebesian valve in the coronary sinus ostium or the Valve of Vieussens in the cardiac veins by tracking over a guide wire. The guide wire can be selected for properties that match the specific situation encountered.

12. Sale or Publication (Needed to establish the date of any printed publication, public use or sale, since no U. S. patent application may be filed after one year from such date.)
- a. If a device has been offered, or will be offered for sale, or used for profit or otherwise publicly disclosed, state when and to whom delivered and how used? Has not been publicly disclosed.
 - b. Has a printed description of this invention been made available to persons outside the company? How and when and was use restricted (e.g. licensing agreement, non-disclosure agreement, proprietary legends, etc.)? No

13. Inventor(s) Signature(s) (REQUIRED):

Signature

John E. Smith
John E. Smith
John E. Smith
John E. Smith
John E. Smith
John E. Smith
John E. Smith
John E. Smith
John E. Smith
John E. Smith

Manager's Comments

14. How is this invention important to your products, plans or goals? _____

15. Manager's Signature (REQUIRED)

Signature

Manager's Printed Name _____

Business Unit _____

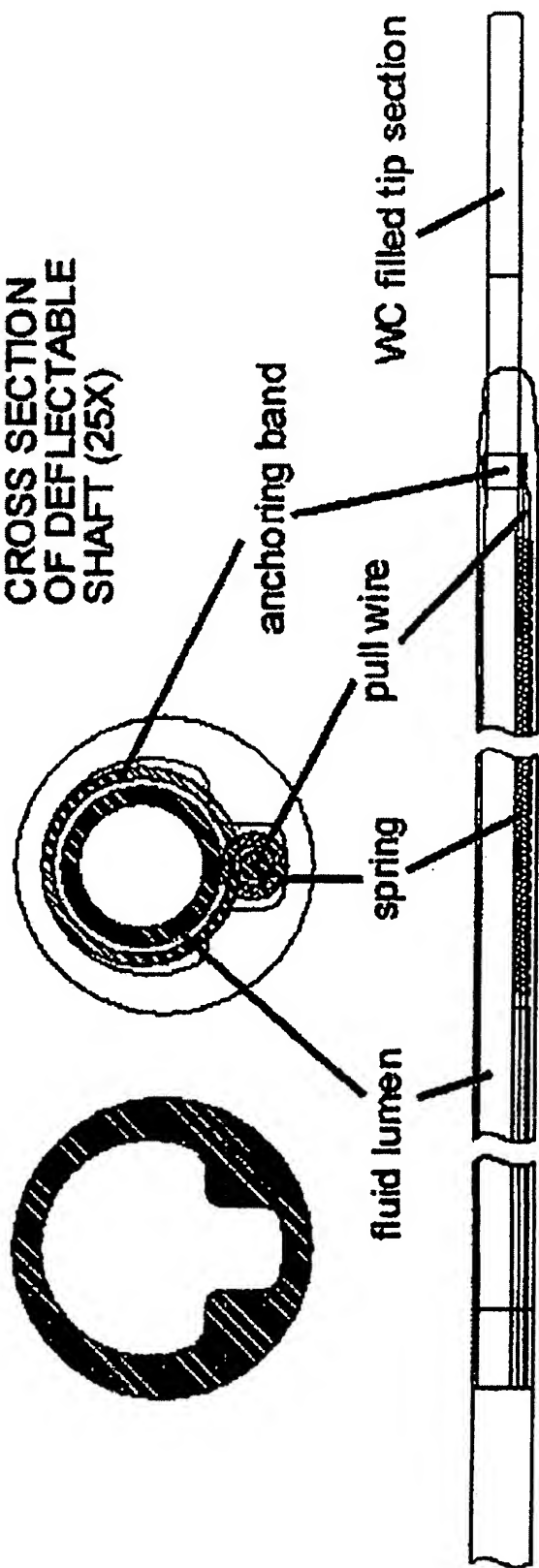
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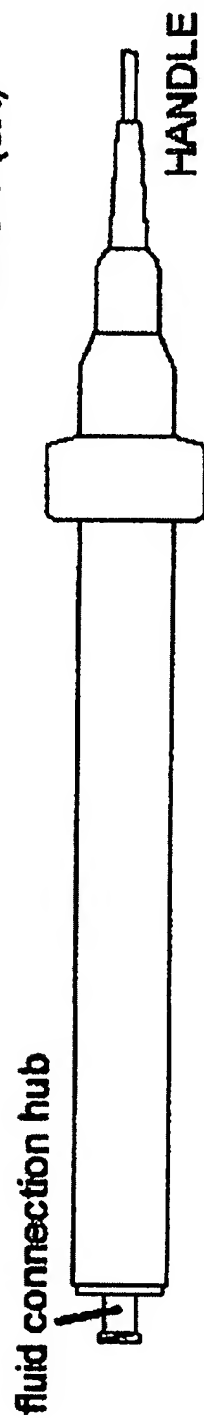
This is a very important disclosure for the business

Manager: Please forward to Patent Section of Law Department, MS 301, upon completion of your review.

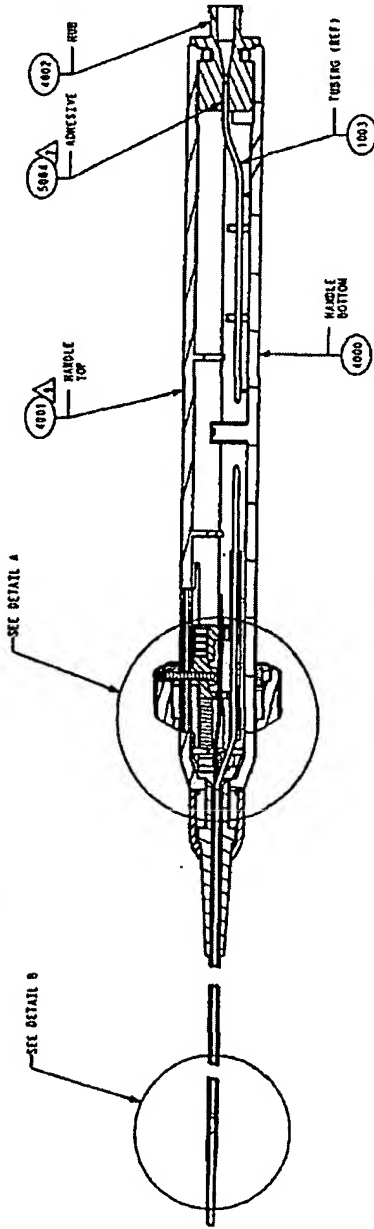
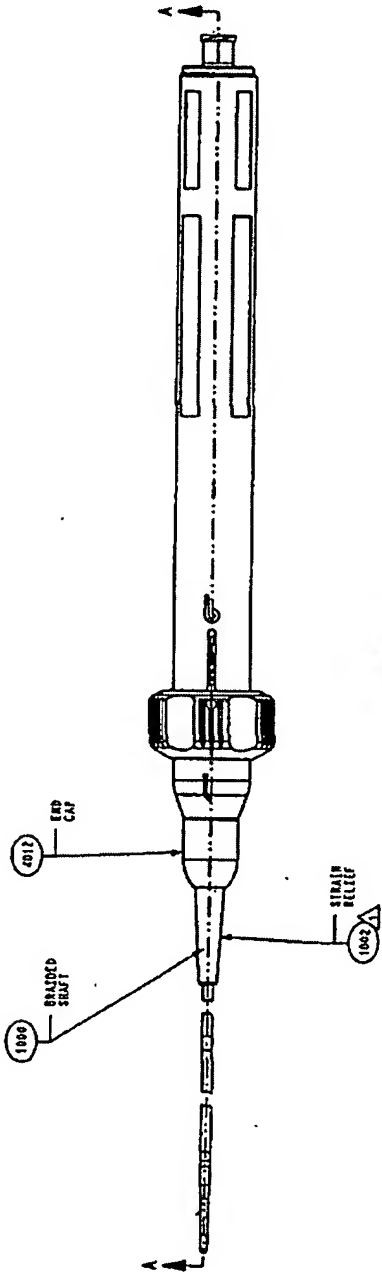
CROSS SECTION
OF DEFLECTABLE
SHAFT (25X)



"SEE THRU" DEFLECTABLE
SHAFT (5X)



REV	DESCRIPTION	DATE	BY	CHKD	APP
1					



SECTION A-A

- △ STRAIN RELIEF, ITEM 1002, IS FUSED TO BRAIDED SHAFT, ITEM 1000.
- △ BRAIDED SHAFT, ITEM 1000, IS FUSED TO JOINT TRANSITION TUBING, ITEM 1005, AND DEFLECTABLE TUBING, ITEM 1001.
- △ WELDED TIP, ITEM 1003, IS FUSED TO TUBING T-LUMEN, ITEM 1001.
- △ HYPODUR, ITEM 1003, IS CRIMPED TO PULL WIRE, ITEM 1001.
- △ PULL WIRE, ITEM 1001, IS WELDED TO STAINLESS STEEL BAND, ITEM 1006.
- △ DEFLECTION TRANSITION TUBING, ITEM 1005, IS FUSED INTO JOINT TRANSITION TUBING, ITEM 1005.
- △ TUBING, ITEM 1003, IS BONDED TO RUB, ITEM 1006, USING ADHESIVE, ITEM 1005.
- △ SLIDER STOP, ITEM 1004, IS BONDED TO HANDLE TOP, ITEM 1001, USING ADHESIVE, ITEM 1005.
- △ HANDLE TOP, ITEM 1001, IS ULTRASONICALLY WELDED TO HANDLE BOTTOM, ITEM 1004.

Medtronic		TITLE	
CATHETER - PREVAIL, STEERABLE, 1 CURVE, LUMEN, IF		503064 A 1-2	
DATE		REV	
10/10/80		10/10/80	
BY		BY	
J. J. J. J.		J. J. J. J.	
CHECKED		CHECKED	
J. J. J. J.		J. J. J. J.	
APPROVED		APPROVED	
J. J. J. J.		J. J. J. J.	
DATE		DATE	
10/10/80		10/10/80	
BY		BY	
J. J. J. J.		J. J. J. J.	
CHECKED		CHECKED	
J. J. J. J.		J. J. J. J.	
APPROVED		APPROVED	
J. J. J. J.		J. J. J. J.	

NOTEBOOK NO. 10313
ISSUED TO John Go!

NT

SCIENTIFIC NOTEBOOK COMPANY
2831 LAWRENCE AVENUE
STEVENSVILLE, MICHIGAN 49127
(800) 537-3028 - <http://www.snco.com>

T Lumen tubing

Project No. B4429
Book No. 10657

Page No. Material Seal 400 Part 010331 102 20% R.O. Blue Fortin
Fortin lt 04102807

Dried at 160°F for 18 hrs —



1" Killian Extruder 1 cc Gear Pump Since 61 die
12-6-6 screws 60-80-100-60 screws

T Lumen
Started with 240 Bk

This Run all done with 240 Bk
maybe slightly larger Bk 245

- 1 350 of
- 2 375
- 3 350
- 4 365
- 5 365
- 6 370
- 7 360
- 8 355
- 9 345
- 10 412

Heats Done Started color but I think
these heats are good

Melt 437
Head 1047
Melt 944
Outlet 1045
die 939

tubing looks good Sent 50 3ft Samples
to John Good on 8/12/02

Run Pump R.P.M 85% 29.7
Extruder RPM 15%
Takeoff FPM 46.9
Quench 104°F
Distance 825
G.P. Power 61
Extruder Power 28
as set — 6 in water

Tool
Drawing
1095987

Roundness less than .001

Witnessed & Understood by me,	Date	Invented by
		Recorded by <u>M. L. L.</u>

TITLE _____

Project No. _____

Book No. _____

Doc No. _____

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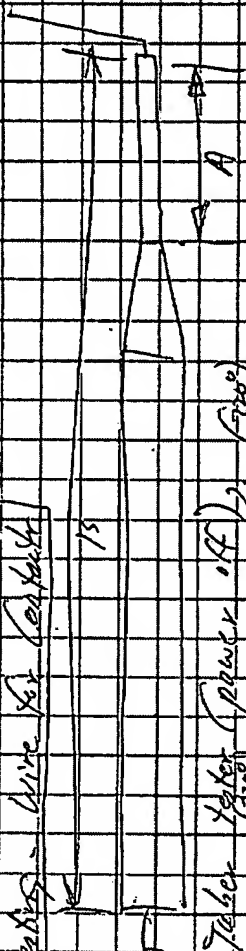
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Torque Testing - Wire for Contact

Method:

Using Torque Tester (power off) 2. (700)
 Torque wire 2x to right, then 2x to left.
 Manually take readings from Torque Tester (5000 lbs units)
 Do not put any weights on the Torque Tester.

Note: Make right angles at end to grip and track torque angle
 ③ Testing 2 of each



Wire	A	B	Right readings (720°)	Left readings (720°)
.025" → .015" → .008"	9 cm	120 cm	15, 11.5	10, 14.5
.025" → .015" → .008"	5 cm	120 cm	18, 18	18, 18
.025" → .015" → .010"	9 cm	120 cm	16.5, 16.5	16.5, 17
.025" → .015" → .010"	5 cm	120 cm	22, 22	22, 22
.025" → .015" → .008"	9 cm	120 cm	9, 8.5	9, 8.5
.025" → .015" → .008"	5 cm	120 cm	12, 14	13, 14
.025" → .015" → .010"	9 cm	120 cm	18, 18.5	17.5, 18.5
.025" → .015" → .010"	5 cm	120 cm	23.5, 22	23.5, 25
.018" → .008" → .005" (5000 lbs units)	9 cm	120 cm	WIRE TOO SHORT	WIRE TOO SHORT
.018" → .008" → .005" (5000 lbs units)	5 cm	120 cm	9, 9	9, 9
.025" → .015" → .008"	110 cm	120 cm	86 @ 210°, 210°	86 @ 210°, 210°
.025" → .015" → .008"	110 cm	120 cm	84, 84	24, 24
.018" → .008" → .005" (5000 lbs units)	140 cm	120 cm	14, 14	14, 14
.018" → .008" → .005" (5000 lbs units)	15 cm	120 cm	8, 7	6, 6.5
.025" → .015" → .008"	15 cm	120 cm	23, 23	22, 23
.018" → .008" → .005" (5000 lbs units)	110 cm	120 cm	1, 8	7, 4
.022 5000 lbs units	110 cm	120 cm	16, 16	16, 16

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Date _____

To Page No. _____

TITLE Prototypes for Attain project

From Page No.____

Prothipon for Aghia Project

Y20320A

butt joint

13030013

20 mm	140	1	97 cm
10	150 mm		

120300 C

76 mm 93 cm

Actual Size

proximal crimp

male roosting here.

The lead ferrite temp: 700°F

To Page No._____

Witnessed & Understood by me,

Invented by

Recorded by

Date

TITLE _____

From Page No. _____		To Page No. _____	
And at	Blunt Fusing	Using Narrow Heat Knife	Machine ES 18229
Machine settings			Pair 0814-201 Cann. Shaft 45430001 M 4728840
(1) Temperature (°F)	Airflow (SCFH)	Compression (psi)	Heat Time (sec)
385	2.5	3.0	60
	braid visible but acceptable		
(2) 380	"	"	"
	braid visible not acceptable		
(3) 385	"	"	"
	TC problem -- replaced TC		
(4) 435	"	"	"
	braid visible not acceptable -- keep pressure a little higher		
(5) 440	"	"	"
	looked good	Tensile 1196 lbr	
(6) repeat			
	looked good	Tensile 1175 lbr	
(7) 440-445	"		
	looked good	Tensile 1138 lbr	
(8) 450-450			
	looked OK	acid visible but not thru surface	Tensile 12.10 lbr
(9) 450			
	looked good	Heat for sample	

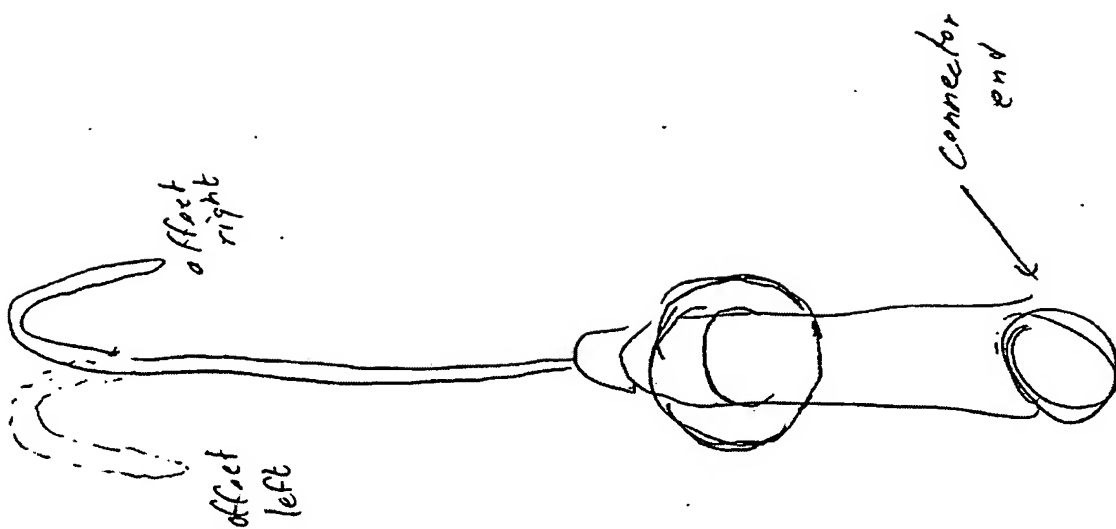
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Date _____

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TITLE _____

Project No. _____

Book No. _____

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From Page No. _____

Cont'd	Protrude Build	Performance	Alterations	Remarks
Sample A	1 Set after straightened (left or right) sample	Secondary Curve Top Offset (degrees) from Reference Curve Length Approach Angle Left or right	Secondary Curve Right Curve Angle	Comments
10 A	13° Left	81 mm	10° Right offset (3.4 mm)	140° 140° 140°
2 A	11° Left	56 mm	5° Right offset (1.2 mm)	255° 140°
12 B	11° Left	90 mm	20° Left offset (4.1 mm)	360° 1650 61.2 mm ENDED WIRE
1 B	12° Left	60 mm	5° Left offset (.6 mm)	135°
12 A	10° Left	103 mm	4° Left offset (1.1 mm)	90°
6 B	9° Left	93 mm	8° Right offset (1.2 mm)	125°
7 B	15° Left	57 mm	5° Right offset (.8 mm)	330° 90° 1400 PIN STOP ADJUSTED DISTAL ANGLE NOW = 143°
2 B	20° Left	55 mm	26° Left offset (5.7 mm)	125°
5 B	20° Left	106 mm	25° Left offset (4.8 mm)	125°
5 A	15° Left	102 mm	41° Right offset (1.3 mm)	133°
1 A	9° Left	62 mm	20° Left offset (4.1 mm)	115°
9 A	14° Left	76 mm	28° Left offset (8.6 mm)	90°
7 A	27° Left	58 mm	17° Right offset (3.4 mm)	90°
4 A	5° Left	78 mm	0°	130°
8 A	10° Left	53 mm	10° Left offset (1.8 mm)	170°
8 B	12° Left	56 mm	15° Left offset (3.37 mm)	140°
3 B	15° Left	83 mm	22° Right offset (4.5 mm)	115°
4 B	5° Left	75 mm	4° Left offset (.8 mm)	180° +
11 A	7° Left	101 mm	5° Left offset (1.4 mm)	90°
9 B	6° Left	80 mm	32° Right offset (5.9 mm)	90°
10 B		75 mm		

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Date _____

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To Page No. _____

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~~Recommendation of architect after for time & discussion~~
Design Review Notes

Recommended curve sizes: 55mm, 70mm, 85mm

may not go with first round of release

60, 75 mm also works on 85mm another possibility - go to extremes

Final word: 60 55mm, 75mm, 85mm

Comments on primary curve values, curve size.

2B: hard to pull, but not impossible - wire starts to buldge thru (does not come thru) at 180° 150° is max curve for this

9B: 270° is no problem - curve feels a little chunky

4B: will go 270° - curve stiffness feels good

2A: curve feels good - will go to 270°

2A: same as 2B

5B: a little chunky - will pull to 270°

2A: a little finer pretty good - could be stiffer - will pull to 270°

12A: too thick, will pull to 270°

10A: a little chunky - will pull to 270°

1A: pretty good stiffness - will pull to 270°

6B: pretty good - could be stiffer

8B: good stiffness, 270° can be pulled but wire starts to buldge thru 180° is no problem

11A: very chunky, 270° can be pulled

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To Page No. _____

TITLE Sprinkler Tip Fusing Qualification

Project No. _____

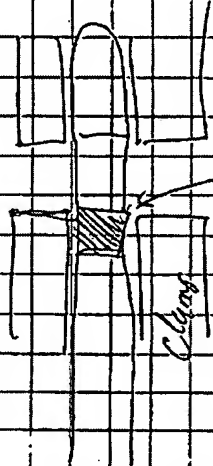
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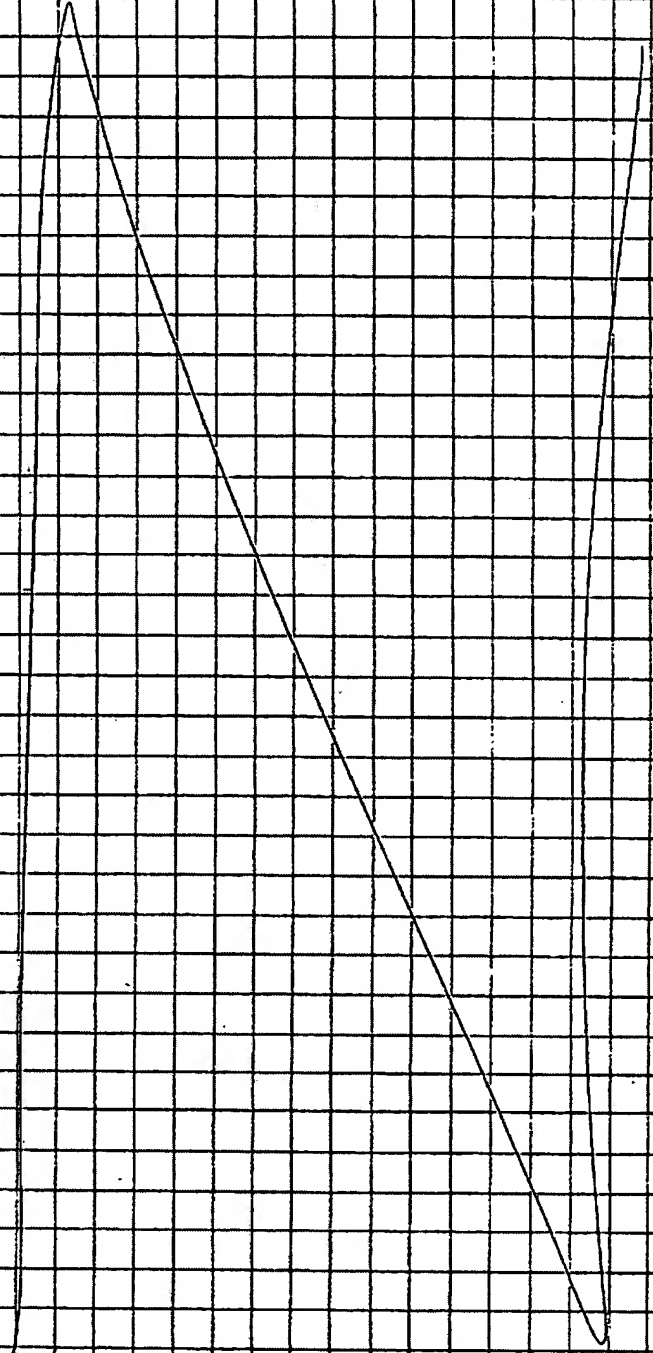
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Sprinkler Tip Fusing Qualification

Added Newark step learned during qualification



line is hand with the edge of the clamp
and recycle for machine.



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TITLE Slider ring pull distances - Rontex

Project No. _____
Book No. 10363

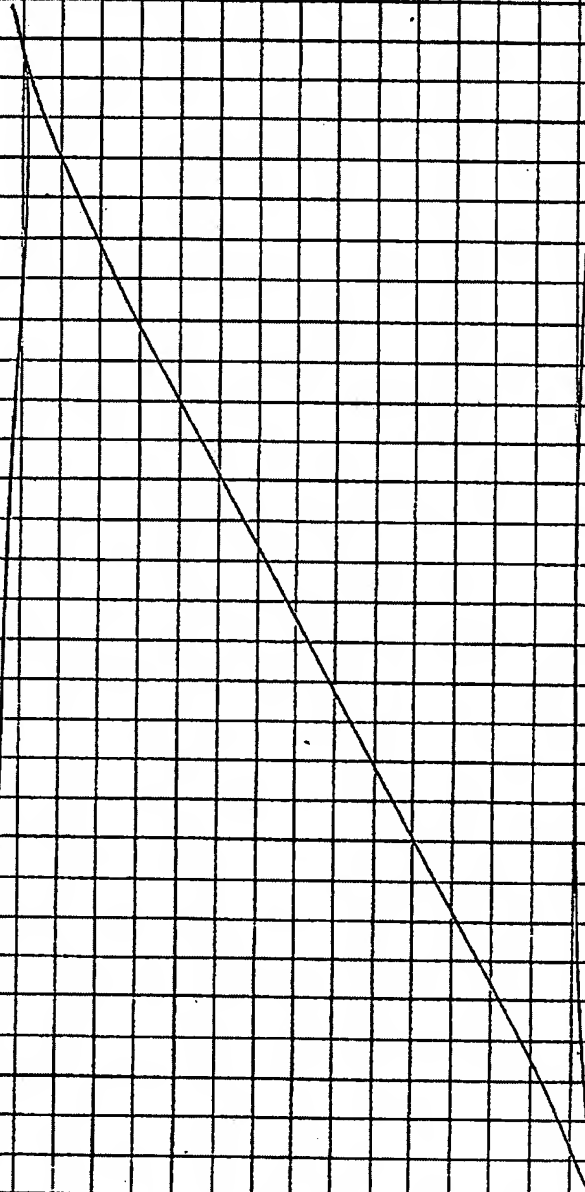
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Model	Slider Ring Pull Distances	Units in inches
588C	Proximal (E 270°)	Distal (E 175°) (load straight)
575C	.530 - .180	.588 - .231
588B	.540 - .174	.583 - .121
465A	.491 - .176	.543 - 0
465A	.536 - .117 (rel peak 270°)	.563 - .100
468A	.539 - .1137	.580 - .100
468A	.530 - .107	.569 - .150

1.757 - 100 - 275

~100"



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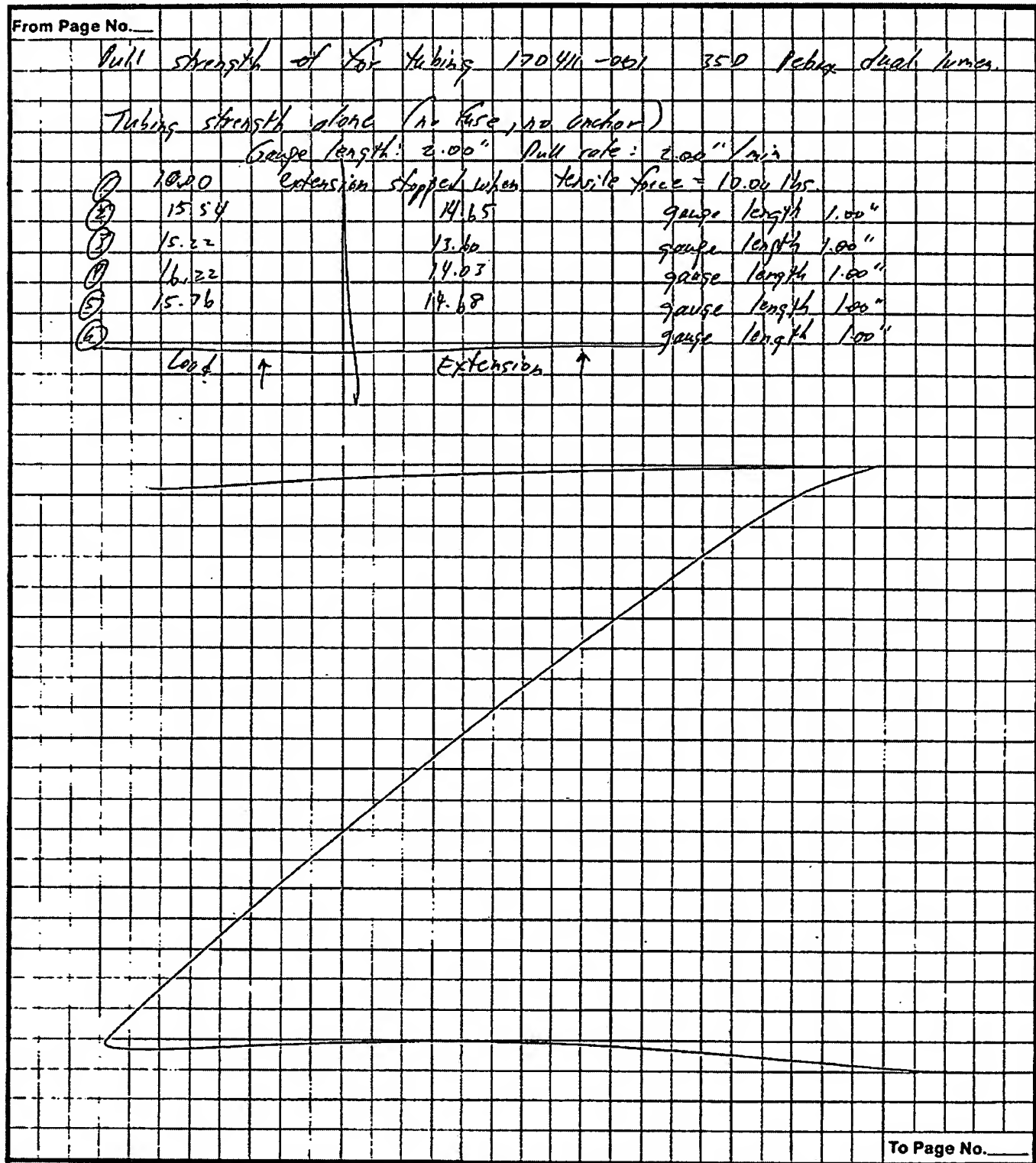
Invented by _____

Date _____

Recorded by _____

TITLE Strength expected at anchor joint

Project No. _____
Book No. _____



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Date _____

Invented by _____

Recorded by _____

Date _____

TITLE Dielectric Strength Testing of wire

Project No. _____

Book No. _____

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From Page No. _____

Test of Cathode w/ salted test solution
minutes: 1.50 kv., .500 ~~24~~ mA trip

Cathode	60-8	.41 high	(pass)
575A		.35 high	(pass)
465A		.32 high	(pass)
60-5		.30 high	(pass)
EPT Maxer TC		.52	(fail)
5031 TM	Lot SK108		
EPT Stepmouth		.35	(pass)
Daig Wirewire TC		.12	(pass)

10 second rise, 10 second dwell

Wire: Daig green

2 KVDC	no leaks
2 KVAC	.13 mA
3.0 KVDC	no leaks
3.5 KVDC	no leaks
4.0 KVDC	no leaks

152961-001

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Date _____

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Date _____

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TITLE Hot Knife Uniformity Study

Project No. _____

Book No. _____

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Machine: ES18482

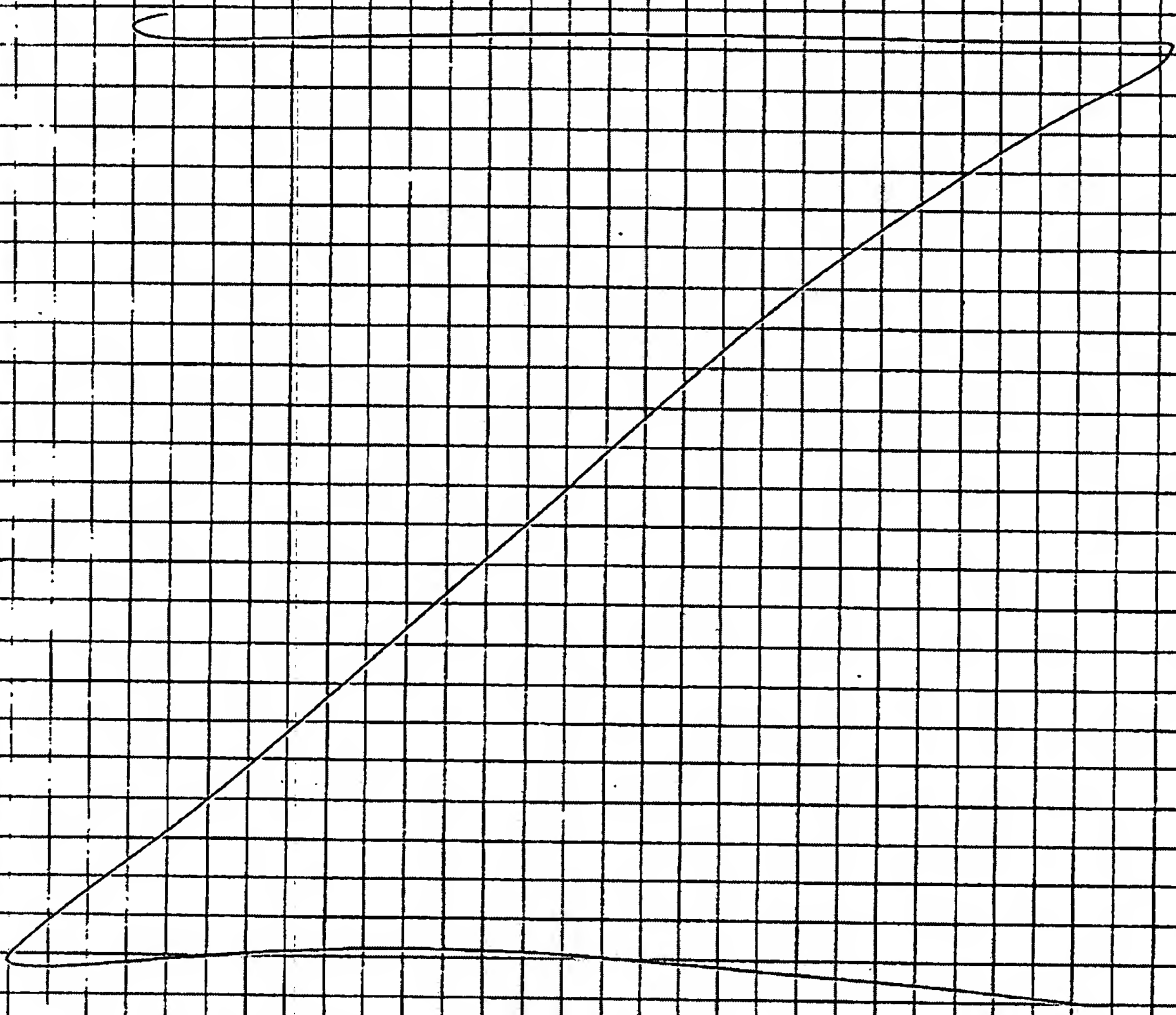
Temperature Setting: 500°F, 25 SCFH

Temperature reading, old thermocouple: 451.3

(Max temp read)

Temperature reading, new thermocouple: 462.0

(Max temp read)



To Page No. _____

Witnessed & Understood by me, _____

Date _____

Invented by _____

Recorded by _____

Date _____

TITLE Contact Tip Fusing - SLP.

Project No. _____

Book No. _____

12

From Page No. _____

Machine used: ES18482

Parameters:

Heat time	Slide tolerance	Air Cool	Total time
40 sec	20 sec	45 sec	60 sec

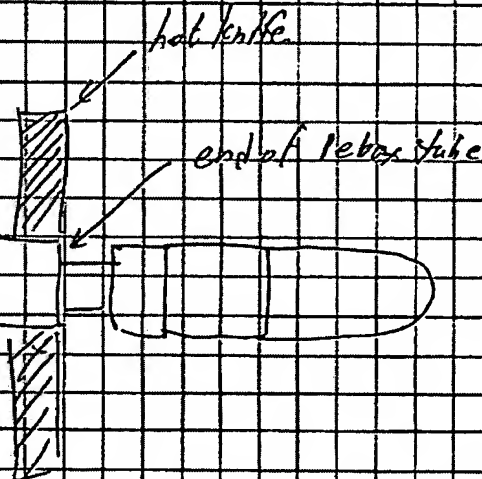
Max vel	0.05 in/sec	Air flow: 20-25 SCFH
Home	-0.05 - 0.08 in	
Wait	40 sec	Temp: 380°F
Home at	0.1 in/sec	
Wait	0 sec	ALL GOOD RESULTS
Max vel	0.05 in/sec	
Home	-0.300 (4 mm)	
Wait	0 sec	
Program End		

Program 2 → 4 mm
 Program 3 → 5 mm
 Program 4 → 8 mm

Note: ES18482 is about
 15°F higher temperature
 setting than R4D lab

ie.:

380 = 365
 ES18482 R4D



Hot knife reading (highest reading) = 350-354°F

To Page No. _____

Witnessed & Understood by me, _____

Date _____

Invented by _____

Date _____

Recorded by _____

From Page No. _____

Evaluation of Out of Plane Deflection in Contact. Proximal Curve

Some catheters sent out for sterilization

(1) 75-5A Proximal Curve EXACTLY IN-PLANE
Distal Curve a little crooked

(2) 2D Proximal Curve in-plane
Distal Curve a little to left (50)
Distal Curve has some straightening

(3) 60-4 Proximal Curve in-plane a little to left - one tip width
Distal Curve in-plane

(4) 60-8E Proximal Curve a little to left - one tip width
Distal Curve in-plane

— all catheters came back from sterilization & are
same

To Page No. _____

Witnessed & Understood by me, _____

Invented by John F. Smith
Recorded by _____

Date _____

TITLE Again prototype build

From Page No. _____

① Pull joint
Gunning
Contact 40.0
Tubing
mandrels .011, .024, .024
temp: 435 430
air flow: 20-25 SCFH
Heat time: 65 sec
Compression delay 70 sec
Cool time: 30 sec
Air pressure 30-35 PSI
Thru block: .105
140

- .018" star crimp diameter.

- 360° for tip wire

To Page No. _____

Witnessed & Understood by me, _____

Date _____

Invented by _____

Date _____

Recorded by _____

From Page No. _____

Purpose: to evaluate the difference in blood coagulation when using Paig, Cordis, & EPS catheters for ablate in thermocouple feedback mode (temperature control)

First set 65°C, 50W power limit

① Paig

② EPS

③ Cordis

Second set 65°C, 50W power limit
3 pictures taken

① EPS average power 13W, Max power 16W.

② Cordis average power 14W, Max power 16W.

③ Paig average power 11W, Max power 13W.

Third set 70°C, 50W power limit
3 pictures taken

① Cordis avg power: 17W max power: 23W

② EPS avg power: 13W max power: 22W

③ Paig avg power: 13W max power: 18W.

To Page No. _____

Witnessed & Understood by me, _____

Date _____

Invented by _____

Recorded by _____

TITLE 8 mm tip snap - Contacts.

Project No. _____

Book No. _____

16

From Page No. _____

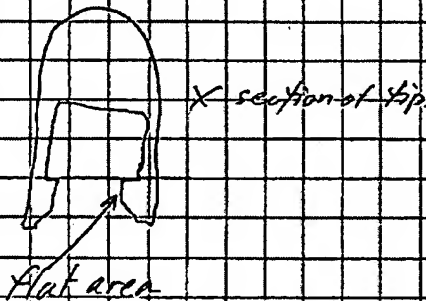
① Comparison of tip snap of Conductr insulator with Contacts insul

Conductr		Contacts	
P/N tip	P/N insul	P/N tip	P/N insul
120168-004	153595-001	120165-004	170343-004
lot 705554	lot 721606	lot 705554	lot 720144

- ① Good - slips thru ring gage
- ② Good - slips thru ring gage
- ③ Slight flare - goes thru ring gage with slight friction

- ① Flared tip edge friction thru ring gage
- ② Slightly flared tip edge
- ③ Good - slips thru ring gage

Conclusion: although the design of the ledge inside the tip electrode (flat area) may contribute to the flaring of the tip, the insulator is most likely the reason for the difference among the snapped assemblies.



To Page No. _____

Witnessed & Understood by me, _____

Date _____

Invented by _____

Recorded by _____

From Page No. _____

Objective: Examine the possible difference between Conductor insulator 170343-004 & Conductor insulator 153595⁰⁰¹ that affects their functionality with 5mm tip 120181-004 and 8mm tip 120168-004. Also examine any possible lot differences or combinations that could affect the fit of the insulator and tip electrode components.

Tip 120181-004	Lot 732812	} ① w/ no adhesive - the prebox snap feature breaks over	
Insulator 170343-004	Lot 720144		
↳ snap feature large diameter: .081" breaking the snap feature w/ quadrachek toolmakers scope .08130		} ② w/ adhesive - tip snapped over insulator without	
Tip 120181-004	Lot 732812		
↳ conductor	Insulator 153158-001	Lot 721608	} ① w/ no adhesive - the tip will snap over the insulator without breaking over the snap feature.
↳ snap feature large diameter: .080" w/ quadrachek toolmakers scope .0803			
Tip 120181-004	Lot 681238	} ① w/ no adhesive - the prebox snap feature breaks over, but not as much.	
Insulator 170343-004	Lot 720144		

Patrick brought up a good point: w/ adhesive, the tip could be reinforced against the insulator edge.

Note: tip snap texture is shifting with new lot of tips.

To Page No. 18

Witnessed & Understood by me,

Date

Invented by

John Fook
 Recorded by

Investigation of Contacts 5mm

Project No. _____

TITLE

5mm tip snap.

Book No. 10363

18

From Page No. 7

Tip Measurements:

5mm tip 120181-001

lot 732812 - will fit .074 - all the time and
.075 - some of the time (depending
on piece part)

120181-001 lot 681238 - will fit .075 - gage pin all of the
time.

8mm tip

120168-004 lot 705554 - will fit .074 - all the time and
(al insul 120713-004 lot 719583) .075 - some of the time (depending
on piece part)

To Page No. _____

Witnessed & Understood by me,

Date

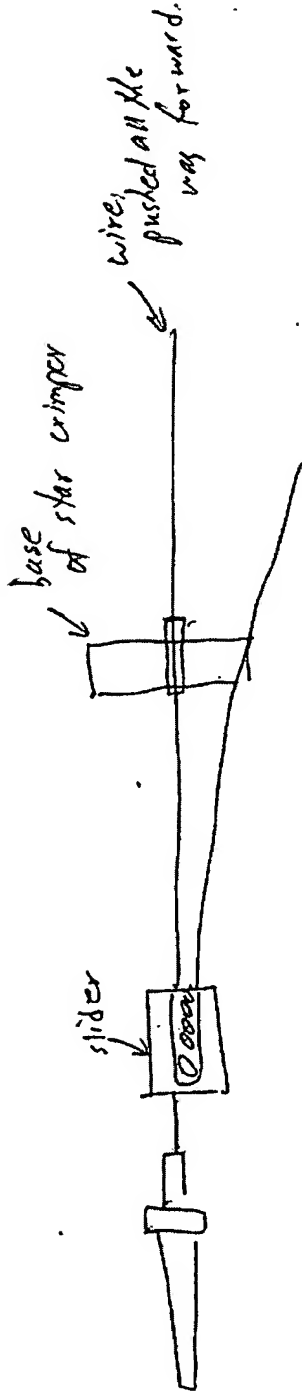
Invented by

Recorded by

D.

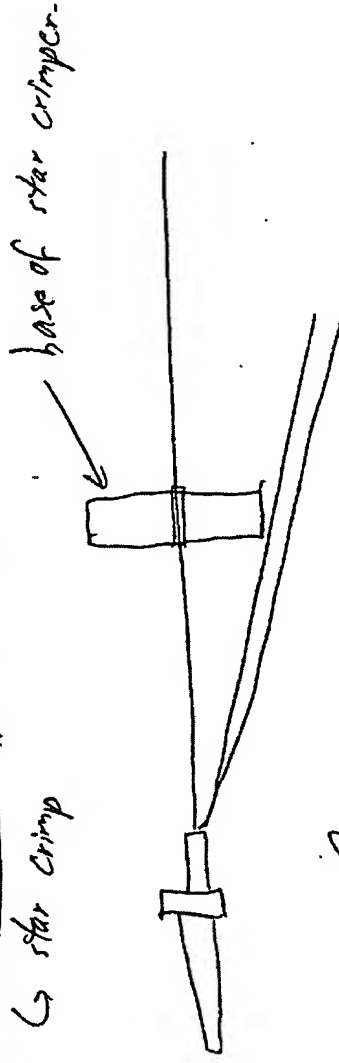
Slide Wire Crimping

↳ star crimp



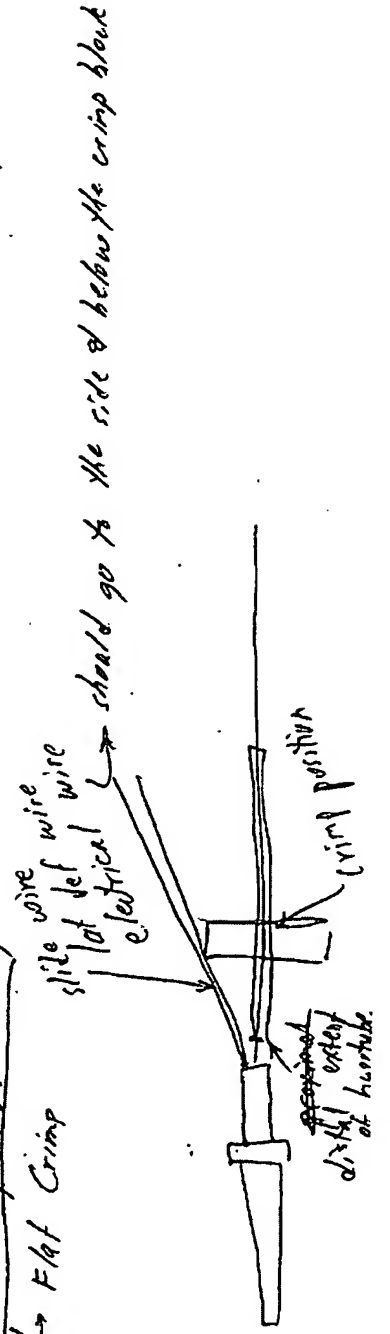
lateral deflection wire hypotube crimp

↳ star crimp



Distal Crimp (Pull wire)

↳ Flat Crimp



From Page No. _____

Pinion w/ adhesive 31.65 lbs
Pinion w/o adhesive 12.01 lbs① Cut tips to 17 cm \pm .5 cm

② Fuse tips

- Mandrels

- Teflon: 2.5 cm

.012", .022", 2K .022"

- Parameters

430°F 20-25 sec 130 throw

Heat 65 sec Press Delay 10 sec Cool Time 30 sec

③ Cut tip to length, Cut shaft to length
↳ 120 mm distal 114 cm④ Fuse, strain relief on shaft
or glue

⑤ Prepare tip

↳ cut tapered wire to length

80 mm

↳ thread tapered wire thru tip insulator head (2310 black)

↳ thread half-ended wire thru tip insulator

↳ apply glue to inside of tip and snap on (need a fixture for tip snap)

⑥ Thread tip and associated wires into catheter shaft

⑦ Thread slide wire into catheter from distal end

Pull wire back from tip a little

⑧ Fuse insulator into tip tubing

↳ done manually - temperature is 360°F need a fixture for this

⑨ Crimp proximal pull wire hypotube onto pull wires

⑩ Crimp lateral deflection hypotube onto lateral deflection wire
↳ Two crimps .012"

⑪ Crimp pull wire slider on

⑫ Crimp slide wire hypotube on. Put slider on and bend

need fixture for bending

Note: for electrically active selectr, cut polyimide .0225 X .0285
to 10.5 cm \pm .1 cm

To Page No. _____

Witnessed & Understood by me, _____

Date _____

Invented by _____

Date _____

Recorded by _____

TITLE Powercap of Africa with elec

From Page No. _____	To Page No. _____
1	Put polyimide sleeve into large funnel. 1025 X 0.85 length 10.5 cm ± 1 cm
2	Slide wire into large funnel beside the point polyimide tape the wire. polyimide and the slide wire pass over at their distal end with this (right) type - this will keep the polyimide from slipping into funnel.
3	Load hard into polyimide and out proximal end
4	put lat deflection and pull wire into insulator and the slide wire into deflector. - the wires must slide then hand make sure wires (mechanical & electrical) are aligned with the tubing that shunt or crossed
5	Load electrical wire ext tip thru insulator and into polyimide wire must go thru head
6	the glue of ring tip to insulator
7	release the thin round polyimide end slide wire it push them into tubing
8	fuse tip

Witnessed & Understood by me, _____	Date _____	Invented by _____	Date _____	Recorded by _____	Date _____
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TITLE _____

From Page No. _____

add 20 mm → tip length 140 mm
untapered wire length 100 mm
crimps of slide wire is 20 mm proximal

add 30 mm → tip length 150 mm
untapered wire length 110 mm
crimps of slide wire is 30 mm proximal

add 40 mm → tip length 160 mm
untapered wire length 120 mm
crimps of slide wire is 40 mm proximal

add 70 mm → tip length 180 mm 150
untapered wire length 120 mm
Crimps of slide wire is 70 mm proximal

To Page No. _____

Witnessed & Understood by me, _____

Date _____

Invented by _____

Date _____

Recorded by _____



TITLE _____

From Page No. _____

Sediment

Irrigated Environments - 5 cases

Fusing Block for

Butt Joint: 140

Total length of deflectable tips \approx 165 mm

Sample #	Intermediate length (mm)	Tip length (mm)	shaft length (cm)
① - 22	115 mm / 550	50 mm / 550 400	98
② - 22	125 mm / 550	40 mm / 550 400	98
③ - 22	135 mm / 550	30 mm / 550 400	98
④ - 22	135 mm / 550	40 mm / 400	97
⑤ - 22	110 mm / 630	25 mm / 400	
⑥ - 22	135 mm / 630	30 mm / 400	
⑦ - 22	110 mm / 550	25 mm / 400	
⑧ - 22	135 mm / 550	30 mm / 400	

To Page No. _____

Witnessed & Understood by me, _____

Date _____

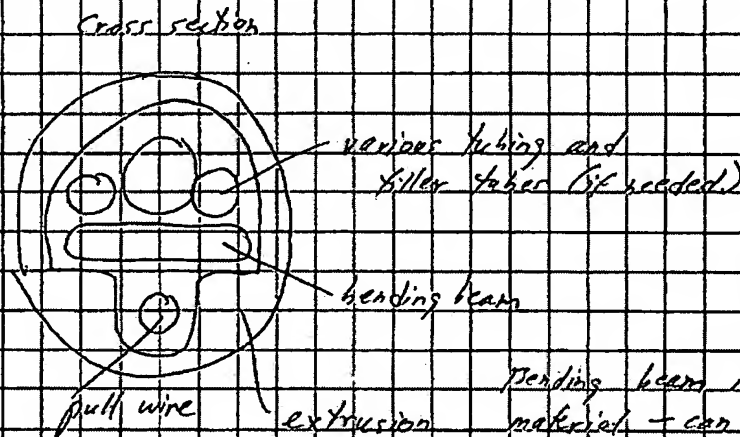
Invented by _____

Recorded by _____

110 / 175 25/30

TITLE Bending BeamBook No. 10763

From Page No. _____



side view - could have molded taper

① - could have molded features

Bending beam is a polymer material - can be molded or cut from sheet. Preferably high diameter material such as ultra (PEU). Advantage - polymer can be molded or easily formed to a tapered shape (thickness or width). Beam can have molded-in features to capture wires or hold other mechanical components in place.

- Variation on bending beam - bending beam with a fluid tube

bending beam general shape:

(cross-section)

bending beam bonded with fluid lumen:



beam bonded to tubing with UV or other suitable adhesive

To Page No. 24

Witnessed & Understood by me,

Shantanu Kumar

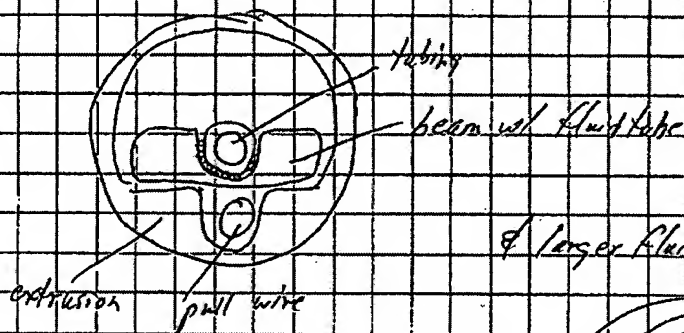
Invented by

Recorded by

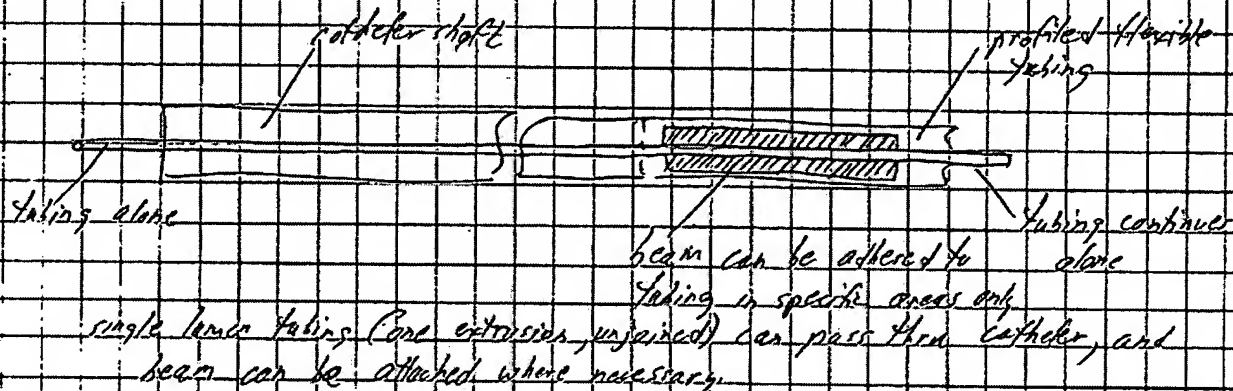
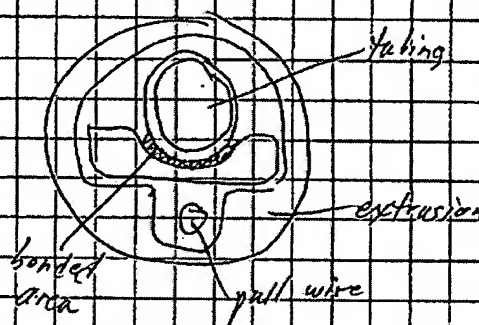
John F. Sub

From Page No. 23

Fluid tube beam in catheter examples:



& larger fluid tube possible



Witnessed & Understood by me

Stanley H. H.

Invented by

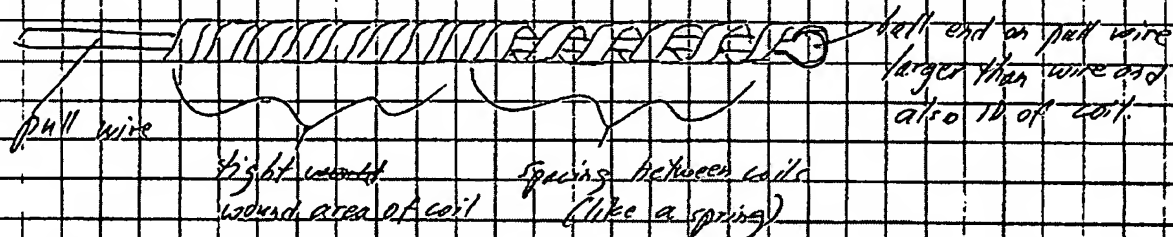
John F. F.

Recorded by

John F. F.

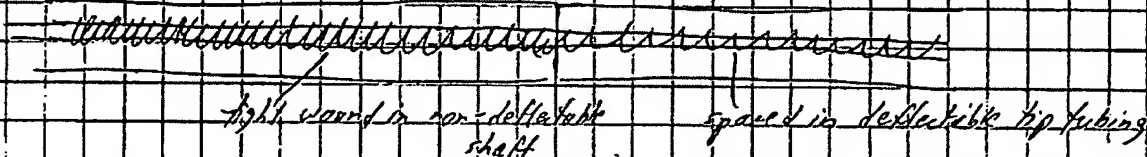
To Page No. _____

From Page No. _____

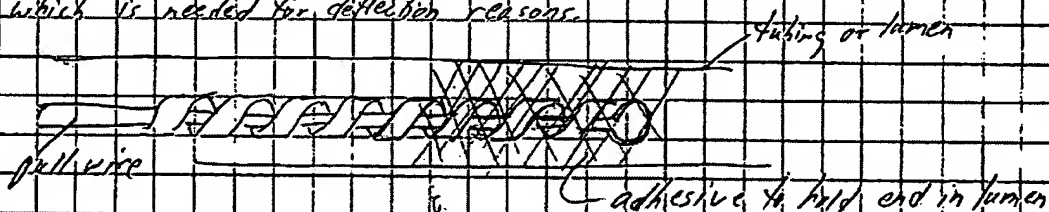


Tight wound coils are positioned inside shaft area that is not intended to be actively deflected with a pull wire.

Spaced coils are positioned inside shaft/tubing area that is intended to be actively deflected. The spaced coils allow compression. When the spaced coils are in a soft deflectable tubing, the coil "adds diameter" to the wire, helping to prevent the wire from slicing thru the wall of the deflectable tubing. The coil is also a surface for the wire to slide over, preventing a sawing of the tubing by the pull wire.



The spaced coils, in combination with a ball on the end of the pull wire, provide a good way to anchor the distal end of the wire, which is needed for deflection reasons.



The spaced coil helps this anchoring because it provides many hard edges and spaces to capture with the adhesive. The ball end on the wire prevents it from slipping thru the coil.

To Page No. _____

Witnessed & Understood by me,

Stank M

Invented by

Recorded by

John J. Sub
John J. Sub

Date

From Page No. _____

Irrigated Safety - 5 curve - T lumen
 Prototype Build.

Butt Joint Fusing

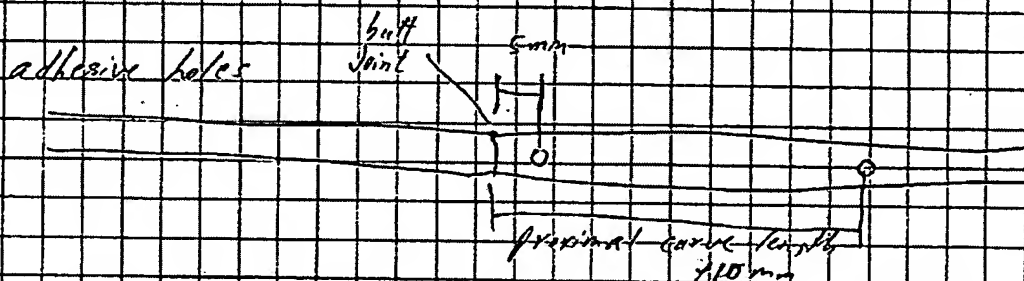
mandrels: .024" x 2, .038"
 temp: 430°F
 heat time: 60 sec
 push time: 15 sec
 cool time: 30 sec
 heat block: .150"

Catheter Configuration

	Proximal Curve Length	Distal Curve Length	
1-26	135	35 30	170
distal pulls proximal,	flat wire length 133,	curves toward	
2-26	135	25	160
distal pulls distal,	flat wire length 133,	curves away	
3-26	110	35	145
distal pulls proximal,	flat wire length 108,	curves toward	
4-26	110	25	135
distal pulls distal,	flat wire length 108,	curves away	

Flat wire welding

.003" x .055" Flat wire Pulse 1: 7.08 Polarity: (+) 7
 Width: 250 Dual Pulse Pulse 2: 0.8 Width: short



To Page No. _____

Witnessed & Understood by me, _____

Date _____

Invented by _____

Date _____

Recorded by _____

TITLE Irrigated Selects - S-curve - Tumors
2nd set of prototypes

From Page No. _____

S-curve prototype Characteristics

Serial #	Overall Length	Deflectable Tip Length (Primary)	Deflectable Tip Length (Secondary)	Comments
----------	----------------	----------------------------------	------------------------------------	----------

27-1	85 cm	140 mm	25 mm	Distal tip length from end to ball on proximal
27-2	85 cm	113 mm	37 mm	pull wires. No radiopaque band. Distal rail not anchored at butt joint.
27-3	85 cm	120 mm	30 mm	Distal end of bending beam not anchored
27-4	85 cm	125 mm	25 mm	

gave to Scott

Single curve flex tip prototypesSoft tip length

27-5	85 cm	110 mm	13 mm	Soft tip material: Pellethane SSD .035X.014
27-6	85 cm	128 mm	13 mm	
27-7	85 cm	126 mm	18 mm	
27-8	85 cm	112 mm	18 mm	

gave to Scott

To Page No. _____

Witnessed & Understood by me,

Date

Invented by

Recorded by

D

Project No. _____

Book No. _____

28

TITLE _____

From Page No. _____

Excise Mandate for T-lumen single curve selector.

.010", .051"

Page No. _____

Witnessed & Understood by me, _____

Date _____

Invented by _____

Recorded by _____

TITLE UV curing process' and fixture

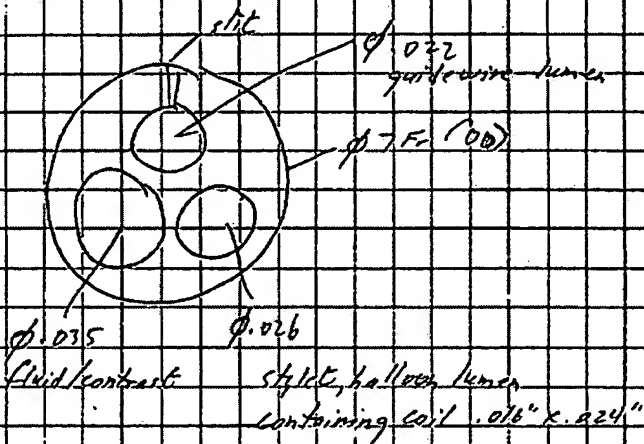
From Page No. _____	To Page No. _____
<p>UV system - 500 W</p> <p>50 seconds (500 W) will heat poly carbonate</p> <p>(Grid)</p> <p>100" x 50"</p> <p>10 seconds</p> <p>UV intensity meter</p> <p>100" x 50"</p> <p>Keep as low as possible</p>	<p>10 seconds</p> <p>UV intensity meter</p> <p>100" x 50"</p> <p>Keep as low as possible</p>

Witnessed & Understood by me, _____
Date _____
Invented by _____
Recorded by _____

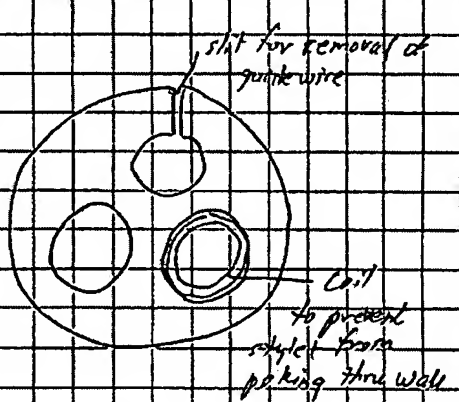
TITLE Guidewire Delivery Catheter.

From Page No.

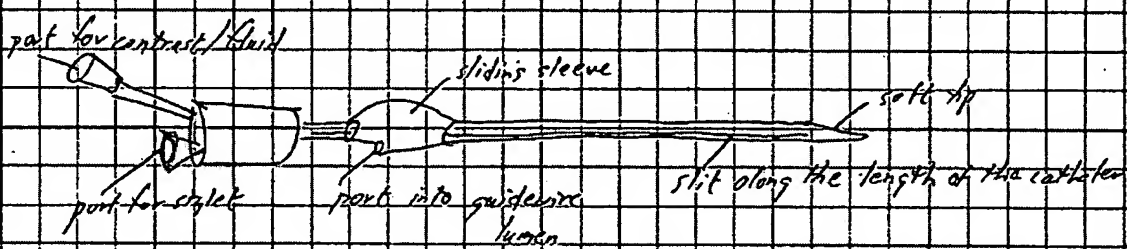
Three lumen catheter



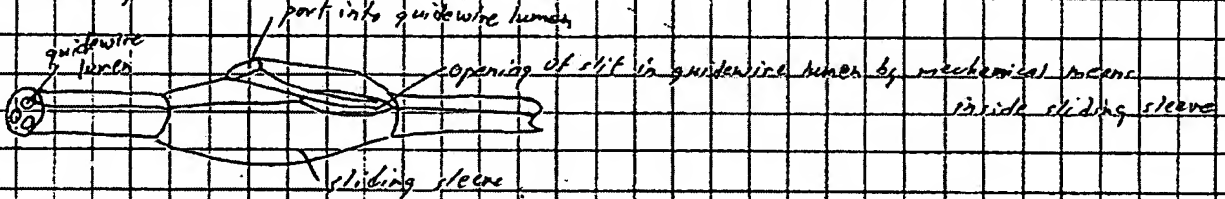
Three lumen catheter with features



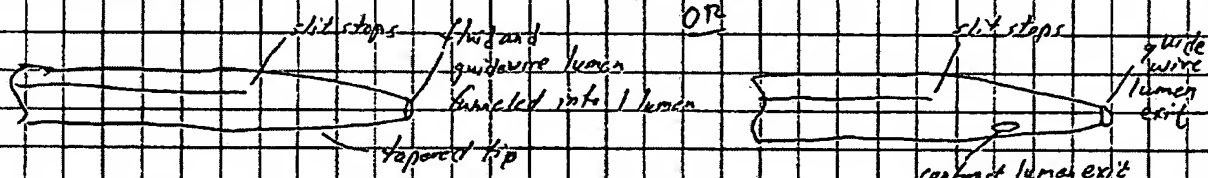
Entire catheter construction



Guidewire port detail



Tip configuration detail



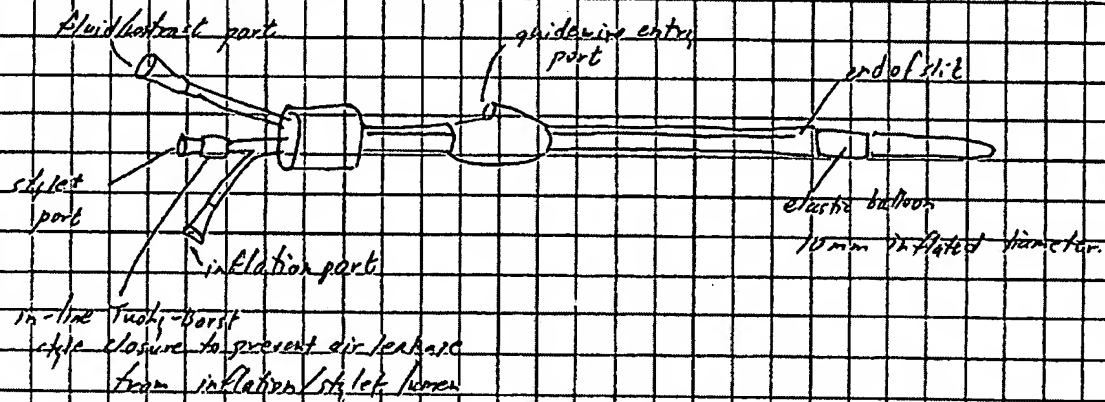
To Page No.

Witnessed & Understood by me, _____

Invented by _____

Recorded by _____

John Ford

TITLE Guidewire delivery Catheter - Balloon OptionFrom Page No. 30*Balloon could be desirable for the purpose of doing occlusive venograms*

Page No. _____

Witnessed & Understood by me,

Date

Invented by

John Jacob

Recorded by

John Jacob

TITLE Angiographic Catheters for Atrial Guides

Book No. _____

From Page No. _____

3 shapes in same package

↳ smaller than typical Angiographic
shorter

↳ all have curves distal enough to allow "multi-plane movement"

Current Atrial Lengths:

add for
for hub/
value

Angiote, Multipurpose: 48.5 cm
 Straight: 45, 50 cm
 ACT MB1: 40 cm
 ACT MB2: 45 cm
 10600: 49 cm

6226 DEF: 52 (total length)
 56 (including valve)

For steerable guides:

Angiographic Catheter designs: SikeSec

Diameter

Working length

shape

6Fr

70 cm

A12

70 cm

Internal Mammary Artery

70 cm

CAS 2 (Cardix shape - Castillon)

70 cm

90° (defined by me)

Cardix Super Torque 6Fr CAS 2

S (defined by me)

90°

"S"

reason

To Page No. _____

Witnessed & Understood by me,

Date

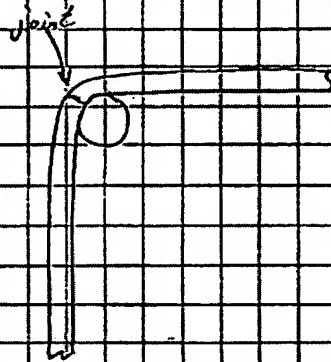
Invented by

Recorded by

TITLE Built Joint Bend Test - Trans:

From Page No. _____

Procedure: Bend joint in 4 directions (approximately 90° to each other)
 over a .250" rod until distal end of joint is 90° to
 tubing proximal of joint - shown below
 Repeat for a total of 8 bends and record observations.



Test Unit	Result
33	
49	
47	
46	white stress line - no brittle failure after continued manipulation (72 total)
45	
41	
37	
42	faint white stress line - no failure after 16 manipulations
40	faint white stress line - no failure after 16 manipulations
44	
36	white stress line - no failure after 16 manipulations
38	faint white stress line - no failure after 16 manipulations
35	
30	
32	
39	white stress line - no failure after 16 manipulations
38	
31	
34	white stress line - no failure after 16 manipulations
43	white stress line - no failure after 16 manipulations

To Page No. _____

Witnessed & Understood by me,

Date

Invented by

Recorded by

John Forb

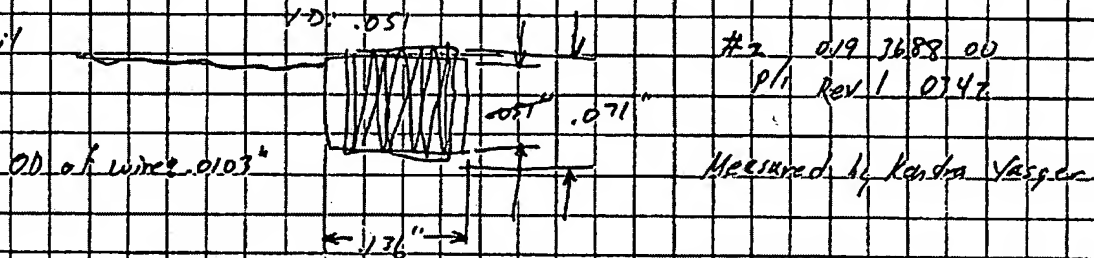
From Page No. _____

Materials:

① SSD Urethane $\text{OD } .091" \pm .001"$, $.006"$ wall.

② 75D Urethane $\text{OD } .038" \pm .001"$, $.004"$ wall.

③ Coil



④ Polyimide $.012" \pm .0005$ wall $.001$
(153587 -) Phelps Dodge

⑤ Adhesive for coils: Loctite 498 (Cyanoacrylate) 168218-001

Polyimide routing under coils:



put polyimide on the same side of the twisted pair

⑥ Extension tube: (ordered from Newark) SPC PVI-S15-1100-CLR

OD: $.096"$ ID: $.062"$

To Page No. _____

Witnessed & Understood by me,

Date

Invented by

Date

Recorded by

TITLE Silicone Valve Investigation

Project No. _____

Book No. _____

35

From Page No. _____

(#1)

Nusil Med 4195

wipe mold & block with 091369-001
(Spray onto towel & wipe)

Injection Pressure 2000 PSI

Plate Temp: 302 °F

Plate Pressure: 2000 PSI

New processing conditions:

Injection: Dayton 42328 D / Kon Archer Press

Plate Temperature: 325°F

Cure time: 3 min

Plate pressure: 2000 psi

To Page No. _____

Witnessed & Understood by me,

Date

Invented by

Date

Recorded by

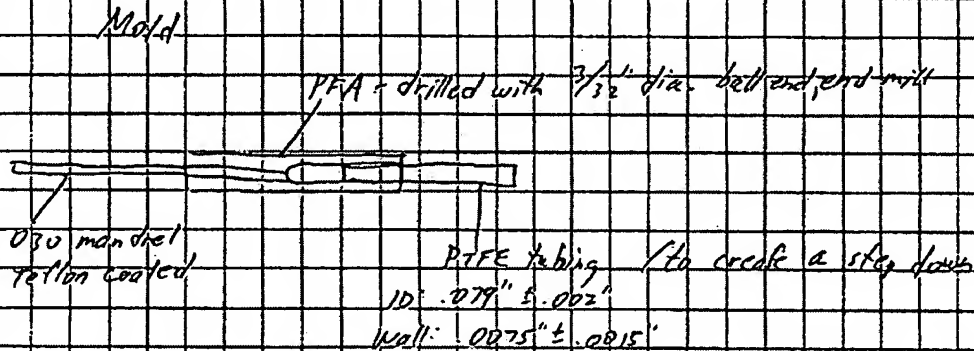
TITLE Forming Lead Nan Insert Tip

Project No. _____

Book No. _____

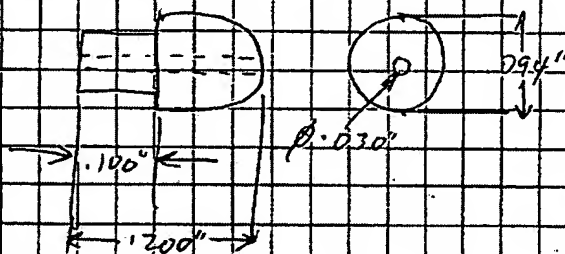
36

From Page No. _____



Part Results:

Material: Cardia Rhythm EX-1652 1-3-86
00711 Atochem Reha 3533 Silver or SN101
20% Barium Sulfate 2 Ea Reed Blue Concentrate
CPUR 02444 and 1/2% TiO₂



Put 0.28\"/>

To Page No. _____

Witnessed & Understood by me, _____

Date _____

Invented by _____

Date _____

Recorded by _____

TITLE Lead Nav Insert Coils Channel Liner

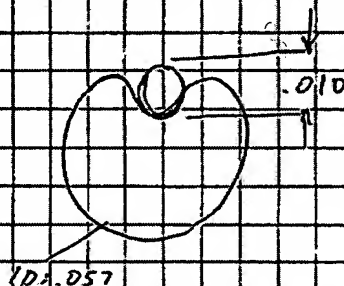
Project No. _____

Book No. _____

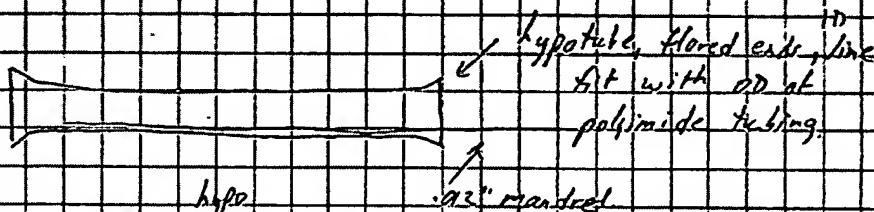
37

From Page No. _____

Objective: Form a liner with a channel that will accommodate a .010" wire



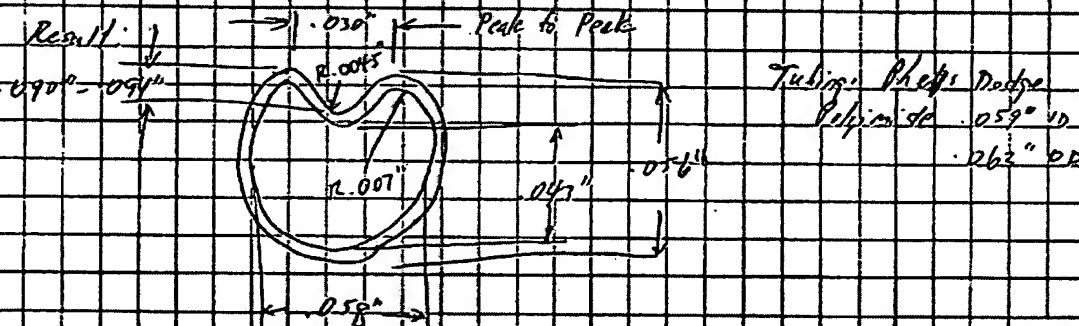
Method:



- ① Push mandrel into tubing, then polyimide using . " mandrel to support polyimide when pushing into hypotube
- ② Heat hypotube to 750°F. Use Lesker Hot Air soldering station Type Hot Jet "S" Digital Lesker CH-6056

③ Cool with factory air

Also, in step 2, pull on mandrel after placing polyimide to make channel more straight along wall (reduces "candy cane" effect).



To Page No. _____

Witnessed & Understood by me, _____

Date _____

Invented by _____

Recorded by _____

TITLE _____

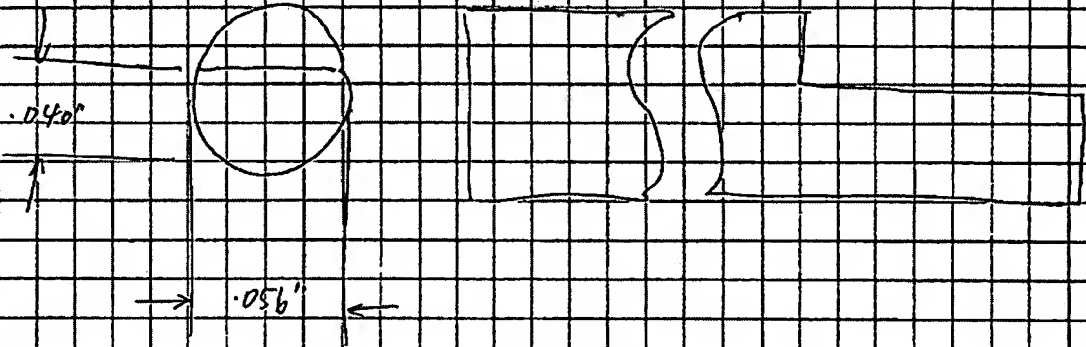
Project No. _____

Book No. _____

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From Page No. _____

Mandrel: .056" OD



To Page No. _____

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Date _____

Invented by _____

Recorded by _____

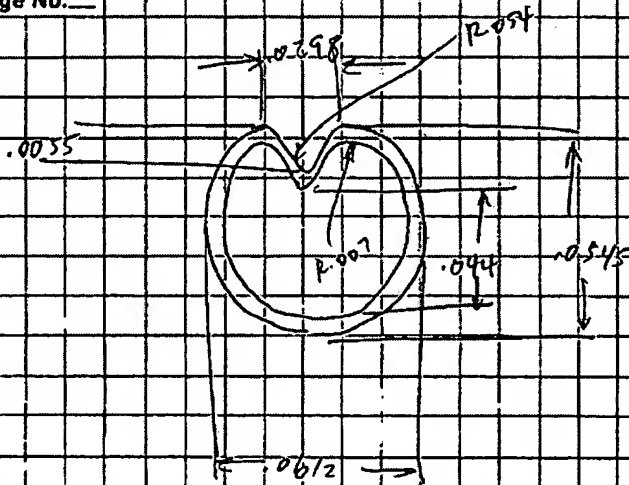
TITLE Lead Navy Channel Liner

Project No. _____

Book No. _____

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Witnessed & Understood by me,

Date

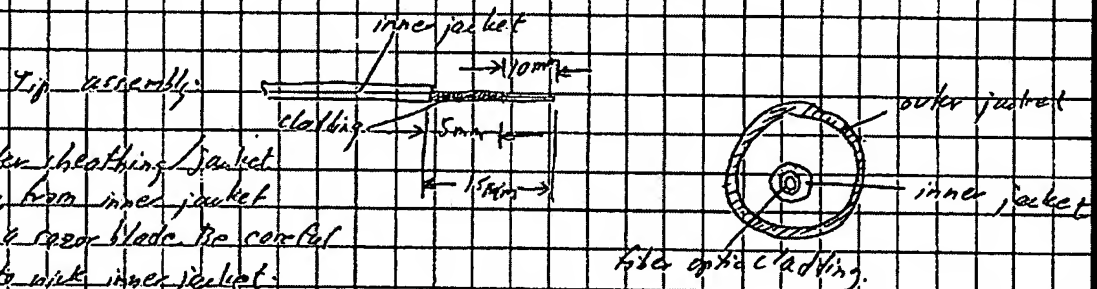
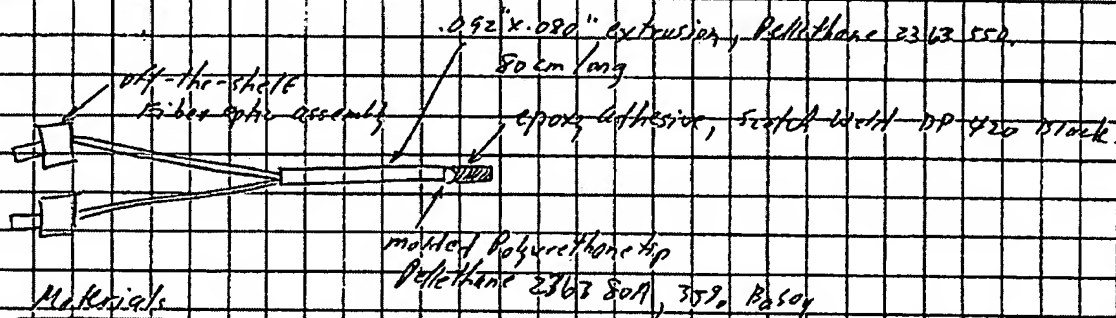
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Date

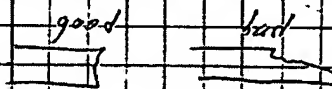
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TITLE Optical Probe Assembly

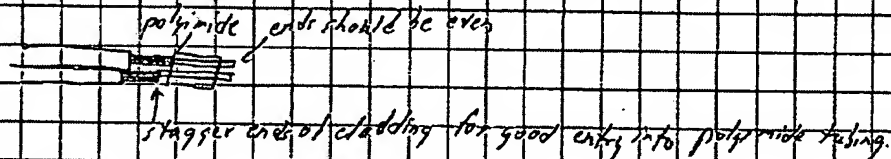
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- ① Cut outer sheathing/jacket away from inner jacket with a razor blade. Be careful not to nick inner jacket. Strip about 85 cm length.
- ② Strip inner jacket using Microstrip .025" hole x .021" blade - strip length: 15 mm.
- ③ Strip cladding using Microstrip .021" hole x .012" blade - strip length: 10 mm.
- ④ Break the end (very tip) of the fiber optic with sharp snips - end of fiber optic should be cut so that long chips or shivers do not go down the length of the fiber optic.



- ⑤ Cut a 5-6 mm piece of polyimide (polyimide .017" x .022" x .001") and slide polyimide over the fiber optic. The fit is snug and it may be best to make the shape of polyimide a little oval by compressing with thumbers.

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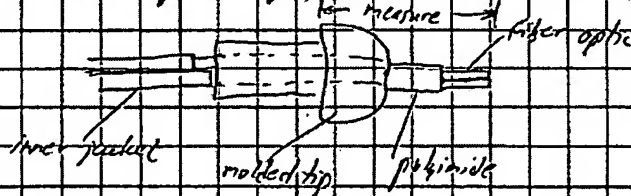
Date _____

Recorded by _____

John Smith

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- First: clean molded tip with isopropyl alcohol and a wipe.
 ⑥ Push molded tip over polyimide and fibers end up to nearest end of inner jacket



note: measure then the end of fiber into to lip of molded tip length.

- ⑦ Fill a piece of PTFE tubing (.085" x .18", 4 in long) with DP 420 black Epoxy. Using static mixer and dispensing gun, dispense epoxy directly into PTFE tubing

- ⑧ Push assembled tip into filled tubing so that epoxy covers the end of the tip and the optical fibers. Continue to push while excluding the open end of the PTFE with finger. Stop pushing when adhesive flows (not barely visible) from the proximal end of the molded tip.

- ⑨ Let assembly cure for 24 hrs. Note: accelerating the cure with heat causes bubbles to grow larger (not good)

- ⑩ Peel PTFE (slice & peel) away from cured adhesive - based on measurement made in step 6, cut epoxy and the rough sand to optical fiber.
 Note: to see optical fibers during rough sanding, must wet the sanded end. Also, can shine light down the proximal end of the fiber.
 If bubbles are present, sand thru the bubbles to remove them.

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Date _____

Invented by _____

Recorded by _____

John F. Smith
John F. Smith

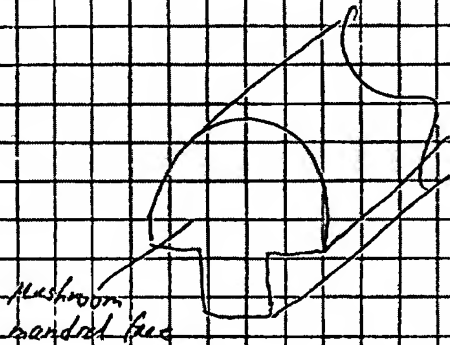
TITLE Braided Mushroom Surca Tubing

Project No. _____

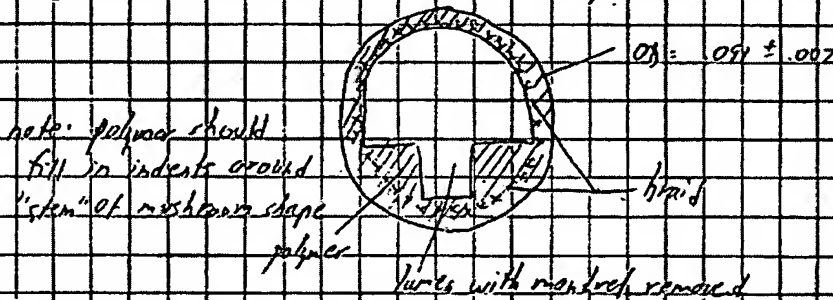
Book No. _____

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- ① Spray mandrel completely with Slide Silicone Mold Release
- ② Use pre-braided braid stretched over mandrel and twist ends of braid
- ③ Slide ^{polymer} jacket over the braid/mandrel
- ④ Fuse the polymer jacket into the braid by sliding FEP heat shrink over the entire entire assembly and heating
- ⑤ Remove the mandrel after fusing
- ⑥ Cross section of the finish assembly should look like:



Try these materials:

- Rebar 40D:
- .002" braid
- .0015" braid (if available)
- polymer braid.

Witnessed & Understood by me, _____

Date _____

Invented by _____

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To Page No. _____

TITLE

Peelable Hub

Project No. _____

Book No. 10363

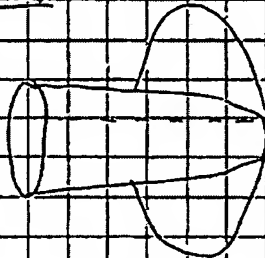
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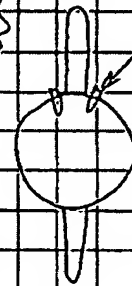
PURPOSE: To create an access point to the shaft that does not go thru
#1 & #2 peel down the axial hub transition point
length of the hub. Top tab is
pulled or manipulated to initiate
tear and a strip is removed

Tear tab

#1

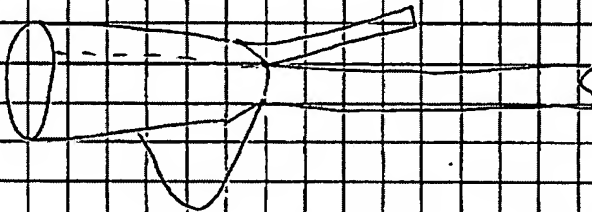


#1 & #2 are different only in
the style of the top tab.



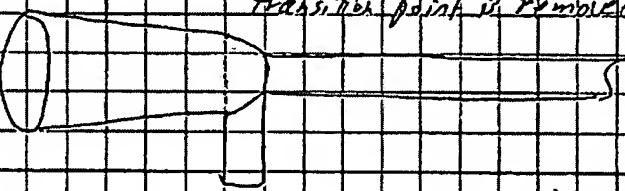
tear "lines"

#2



tear lines

#3

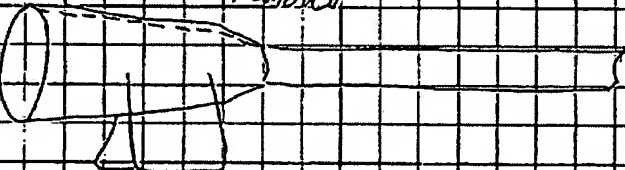


#3 peels circumferentially around the hub - full access from
the proximal end of the hub is not created - but the
transition point is removed.

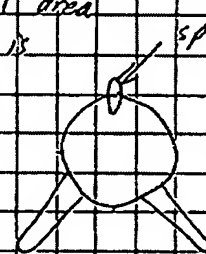


tear line
(circumferential)

#4



#4 creates access from the proximal area
of the hub to the shaft - no material is
removed



split tear line

Witnessed & Understood by me,

Brian B.

Invented by

Recorded by

John J. [Signature]

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→ Ablation, then fusing

to mill

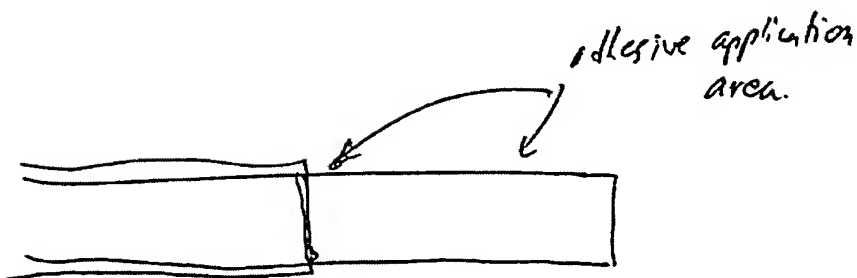
Compression causes "Chinese Finger cuff"

effect if braid is not held down -

may be the reason for using shrink

tubing, then grinding. (get ^{axial} no compression
that way.) only radial compression

Otherwise EPO TEC 390 does a
good job.



Note: Danvers does the overlay
successfully - ^{without compression} used: uses
shrink tubing

Apply adhesive with ~~myet~~ inkjet.

6 mm cut tip

Temp: 400°F

TC Insulation: PET

Polyester Shrink Tubing - clear.

Advanced Polymers

AVG ID: 14 Mils

AVG wall: .23 Mils.

Item: 014023 CST Lot 980227 #1

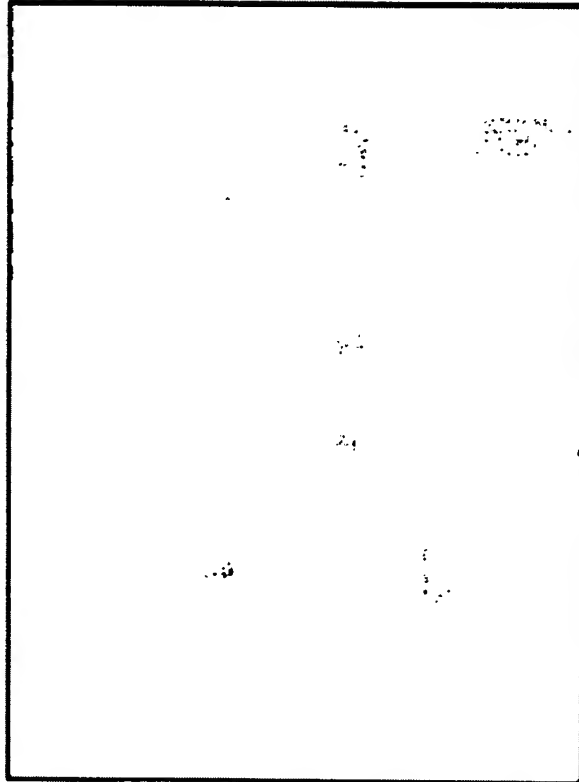
Shrink over bare end of TC at 500°F

4mm cut

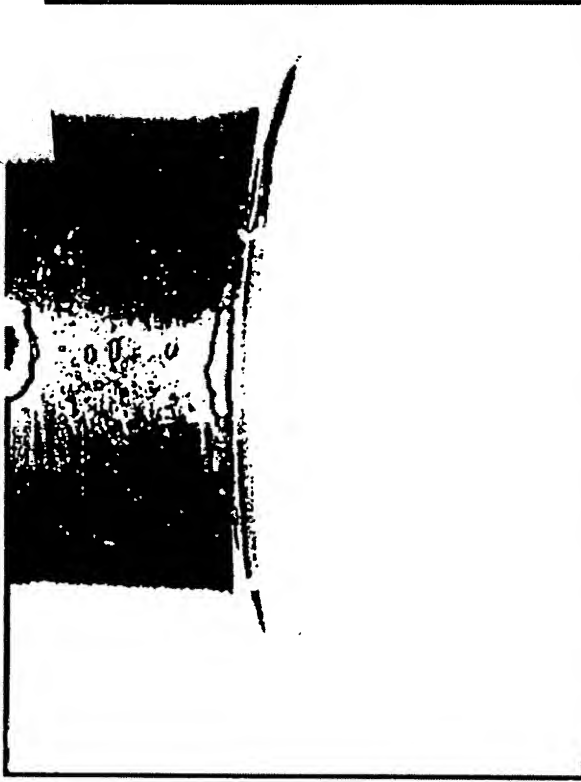
400°F melt

330°F reflow / relax

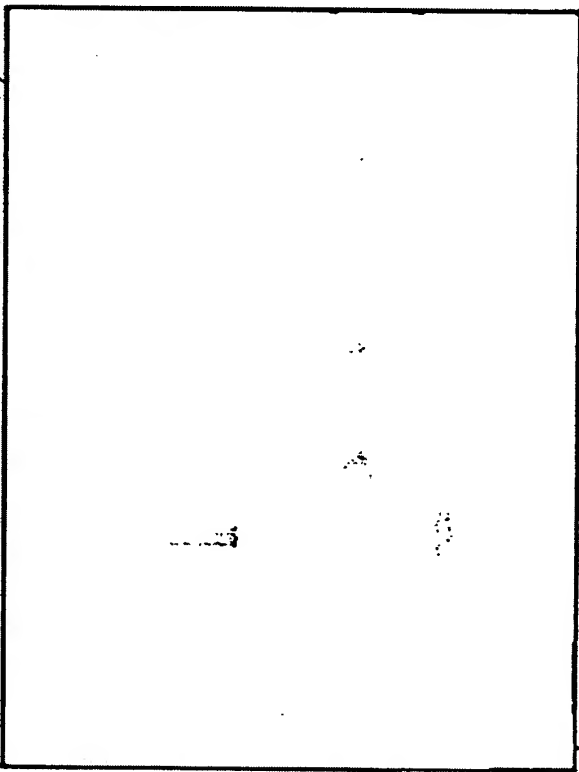
HA1022 701 809122:701
H00-651061 1954/ 100-651851 1954/



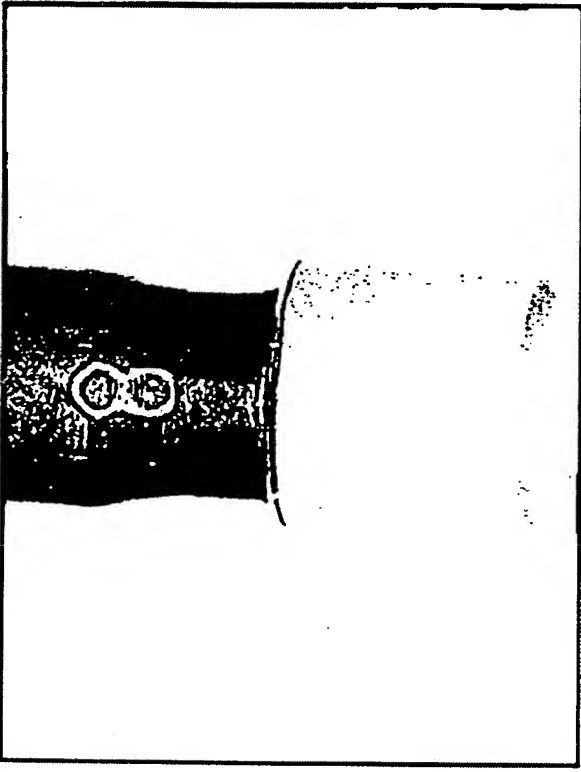
← Same as, closer image



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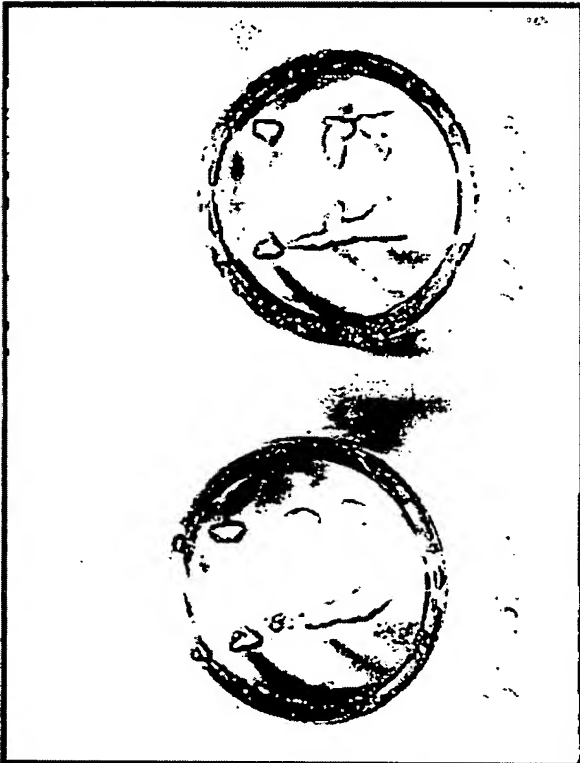




Tip 120181-004 lot 732812



Tip 120181-004 lot 681238



Tip 120181-004

